UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

FILED ELECTRONICALLY

BON SECOURS HEALTH SYSTEM, INC.

BON SECOURS - ST. FRANCIS XAVIER HOSPITAL, INC.

ST. FRANCIS HOSPITAL, INC.

and

ST. FRANCIS PHYSICIAN SERVICES, INC.

Plaintiffs

V.

PURDUE PHARMA L.P.
Serve:
The Prentice-Hall Corporation System, Inc.
251 Little Falls Drive
Wilmington, DE 19808

PURDUE PHARMA, INC.
Serve:
The Prentice-Hall Corporation System, Inc.
80 State Street
Albany, NY 12207-2543

PURDUE FREDERICK COMPANY, INC.
Serve:
The Prentice-Hall Corporation System, Inc.
251 Little Falls Drive
Wilmington, DE 19808

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

MDL No. 2804

Case No. 17-md-2804

COMPLAINT

JURY TRIAL DEMANDED

CEPHALON, INC.
Serve:
Corporate Creations Network Inc.
3411 Silverside Road
Tatnal Building, Suite 104
Wilmington, DE 19810

TEVA PHARMACEUTICAL INDUSTRIES, LTD.
Serve: Teva Pharmaceutical Industries, Ltd.
5 Base Street
Petach Tikva, Israel 49131

TEVA PHARMACEUTICALS USA, INC.
Serve:
Corporate Creations Network Inc.
3411 Silverside Road
Tatnal Building, Suite 104
Wilmington, DE 19810

JOHNSON & JOHNSON
Serve:
Johnson & Johnson
One Johnson & Johnson Plaza,
New Brunswick, NJ 08933

JANSSEN PHARMACEUTICALS, INC.
Serve:
CT Corporation System
600 N. 2nd Street, Suite 401
Harrisburg, PA 17101-1071

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.
Serve:
CT Corporation System
600 N. 2nd Street, Suite 401
Harrisburg, PA 17101-1071

JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.
Serve:
Oliver Building
Mellon Square
c/o CT Corporation System
Pittsburgh
Allegheny, PA 15222-0

NORAMCO, INC.
Serve:
The Corporation Trust Company
Corporation Trust Center
1209 Orange St.
Wilmington, DE 19801

ENDO HEALTH SOLUTIONS INC.
Serve:
The Corporation Trust Company
Corporation Trust Center
1209 Orange St.
Wilmington, DE 19801

ENDO PHARMACEUTICALS, INC.
Serve:
The Corporation Trust Company
Corporation Trust Center
1209 Orange St.
Wilmington, DE 19801

ALLERGAN PLC f/k/a ACTAVIS PLS
Serve:
Clonshaugh Business and
Technology Park
Coolock, Dublin D E400

WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.
Serve:
CT Corporation System
818 W. Seventh Street, Suite 930
Los Angeles, CA 90017

WATSON LABORATORIES, INC.
Serve:
Corporate Creations Network, Inc.
8275 South Eastern Avenue, #200
Las Vegas, NV 89123

ACTAVIS LLC
Serve:
Corporate Creations Network, Inc.
3411 Silverside Road, Suite 104
Wilmington, DE 19810

ACTAVIS PHARMA, INC. f/k/a
WATSON PHARMA, INC.
Serve:
c/o Corporate Creations Network, Inc. 3422 Silver Road
Tatnal Building, Suite 104
Wilmington, DE 19810

DEPOMED, INC.
Serve:
Arthur J. Higgins
7999 Gateway Blvd, Ste 300
Newark, CA 94560

MALLINCKRODT PLC
Serve:
3 Lotus Park, The Causeway
Staines-upon-Thames TW18 3AG
United Kingdom

MALLINCKRODT LLC
Serve:
The Corporation Trust Company
Corporation Trust Center
1209 Orange St.
Wilmington, DE 19801

McKESSON CORPORATION
Serve:
CSC Lawyers Incorporating Service
Megan Bretz
2710 Gateway Oaks Drive, Ste 150N
Sacramento, CA 95833-3505

CARDINAL HEALTH, INC.
Serve:
Cardinal Health 107, Inc.
7000 Cardinal Place
Dublin, OH 43017

AMERISOURCEBERGEN DRUG CORPORATION
Serve:
The Corporation Trust Company
Corporation Trust Center
1209 Orange St.
Wilmington, DE 19801

COLLEGIUM PHARMACEUTICAL, INC.
Serve:
Corporation Service Company
100 Shockoe Slip
2nd Floor
Richmond, VA 23219

and

MIAMI-LUKEN, INC.
Serve:
William Powers
265 Pioneer Blvd.
Springboro, OH 45066

Defendants

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Come the Plaintiffs, Bon Secours Health System, Inc.; Bon Secours - St. Francis Xavier Hospital, Inc.; St. Francis Hospital, Inc.; and St. Francis Physician Services, Inc. (collectively, "**Plaintiffs**"), by and through counsel, and hereby bring this Complaint against Defendants, Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Cephalon, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutical Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Depomed, Inc.; Mallinckrodt PLC; Mallinckrodt LLC; McKesson Corporation; Cardinal Health, Inc.; AmerisourceBergen Drug Corporation; Collegium Pharmaceutical, Inc.; and Miami-Luken, Inc. (collectively, "**Defendants**"), alleging as follows:

I. INTRODUCTION

1. The United States is in the midst of an opioid[1] epidemic caused by Defendants' unlawful marketing, sales, and distribution of prescription opioids that has resulted in addiction, dependency, criminal activity, serious health issues, and loss of life.

2. Plaintiffs bring this civil action to recover monetary losses that have been incurred, and will continue to be incurred, as a direct and proximate result of Defendants' false, deceptive, and unfair marketing and/or unlawful diversion of prescription opioids. Such economic damages were foreseeable to Defendants and were sustained because of Defendants' unlawful actions and omissions, which amounted to wanton, grossly negligent

[1] As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic, and semi-synthetic opiates.

conduct; which constituted negligence, *per se*; fraud; and the South Carolina Unfair Trade Practices Act; and which was violative of both State and Federal law.

3. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid overdose deaths, addictions, and dependencies.[2]

4. The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[3]

5. Plaintiffs bring this suit against the manufacturers of prescription opioids. The manufacturers aggressively marketed highly addictive, dangerous opioids, falsely representing to practitioners that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded practitioners to prescribe highly addictive, dangerous opioids, causing drug addiction and dependency for these companies' own corporate profit. Such actions were unlawful.

6. Plaintiffs also bring this suit against the wholesale distributors of these highly addictive drugs. The distributors and manufacturers unlawfully breached their legal duties under federal law to monitor, detect, investigate, refuse, and report suspicious orders of prescription opiates.

7. Plaintiffs have incurred substantial expenditures, for which they have not received compensation or reimbursement, in connection with their provision of care to individuals who have been impacted by the opioid epidemic being perpetuated by the Defendants.

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[2] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain-Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).
[3] *See* Robert M. Califf et al., A Proactive Response to Prescription Opioid Abuse, 374 N. Eng. J. Med. 1480 (2016).

8. As a direct and proximate result of the foregoing, Defendants have foreseeably caused damages to Plaintiffs including but not limited to the following: (a) unreimbursed and/or uncompensated costs incurred for the treatment of patients who suffer from conditions related to or caused by opioid use; (b) unreimbursed and/or uncompensated costs incurred for the treatment of patients, whose conditions are managed through the prescribing of long-term opioid use and the complications suffered by those patients as a result of long-term use of opioids; (c) unreimbursed and/or uncompensated costs incurred for the treatment and management of patients under the influence of opioids or suffering complications as a result of opioid use or misuse; (d) unreimbursed and/or uncompensated costs incurred for the treatment of patients including children whose medical conditions and complications may be caused by or exacerbated by the use of opioids by others; (e) unreimbursed or uncompensated costs of providing additional treatments and services including therapeutic and prescription drug purchases; (f) unreimbursed and/or uncompensated costs incurred for the provision of laboratory and other diagnostic testing for the treatment and/or management of patients using opioids or undergoing therapeutic interventions to address opioid use or misuse; (g) unreimbursed and/or uncompensated costs incurred for the emergency treatment of patients with opioid-related addiction, disease, or dependency, including but not limited to emergency healthcare services provided for opioid overdose or for patients seeking treatment with opioids due to addictions, dependencies, and/or misuse; (h) unreimbursed and/or uncompensated costs incurred for the treatment with life support-related healthcare services to prevent death in certain instances of opioid overdose, including but not limited to treatment for babies born with addictions and dependencies; (i) the increased costs due to providing necessary

screening procedures for acceptance of patients due to the high prevalence of individuals suffering from opioid-related addiction, disease, or dependency and needing medical care; (j) increased costs related to the monitoring of patients; (k) increased costs related to the credentialing and monitoring of healthcare providers; (l) increased costs related to additional security to address public safety concerns, particularly in the emergency department; (m) increased costs related to the storage and safekeeping of controlled substances; (n) increased costs related to added regulatory compliance; (o) increased litigation defense costs; (p) increased costs related to the procurement and maintenance of insurance; (q) lost revenue attributable to the required discharge of patients who are diverting and/or using opioids in a manner which does not comply with their prescribed use; (r) lost opportunity costs; (s) the diversion of assets from the provision of other needed health care; (t) increased human resources costs, as well as loss of employee productivity; (u) uncompensated research cost related to non-opioid treatment alternatives; (v) uncompensated cost and expense for the provision of non-opioid treatment alternatives in the future; (w) uncompensated cost and expense for the current and future provision of treatment to address the consequences of opioid addiction and dependency, including but not limited to the after-effects attributable to medication assisted therapies; and (x) uncompensated cost and expense for the current and future provision of treatment to patients suffering from opioid withdrawal and/or medical issues related to opioid withdrawal.

II. PARTIES

III. PLAINTIFFS

9. Bon Secours Health System, Inc. ("**BSHSI**"), is a non-profit corporation organized under the laws of the State of Maryland, with its principal place of business in Maryland. BSHSI, through its Affiliates and Health Care Providers, provides for the health care needs of people in the United States and seeks to deliver exemplary outcomes in terms of both clinical quality and patient experience. BSHSI also works across the healthcare continuum to provide improved population health through its Affiliates and Health Care Providers offering direct care services. In February 2018, BSHSI was recognized by the Ethisphere Institute, a global leader in defining and advancing the standards of ethical business practices as one of "2018 World's Most Ethical Companies." BSHSI is one of only eight honorees in the healthcare industry to be so recognized, underscoring the organization's commitment to lead with integrity, as well as its prioritization of ethical business practices. BSHSI is committed to building healthy communities, to transforming the health delivery system to ensure high standards of clinical care, and to the exemplary coordination of patient care.

10. Bon Secours - St. Francis Xavier Hospital, Inc. ("**SFXH**"), is a non-profit corporation organized under the laws of the State of South Carolina, with its principal place of business in South Carolina. SFXH operates an acute care hospital located in Charleston and provides important emergency medical services through its emergency department to the residents of South Carolina in addition to extensive general outpatient services. SFXH serves a community with high unemployment and low income. In conjunction with

BSHSI, SFXH is committed to creating communities of health, hope and well-being and providing access to quality health care services to support healthy communities.

11. St. Francis Hospital, Inc.("**SFH**") is a non-profit corporation organized under the laws of the State of South Carolina, with its principal place of business in South Carolina. SFH operates and acute care hospital located in Greenville and provides important emergency medical services through its emergency department to the residents of South Carolina in addition to extensive general outpatient services. SFH serves a community with high unemployment and low income. In conjunction with BSHSI, SFH is committed to creating communities of health, hope and well-being and providing access to quality health care services to support healthy communities. In March 2018, SFH was recognized by Watson Health, a program evaluating performance metrics to determine top performers in healthcare organizations, as one of the 100 Top Hospitals in the United States. This achievement demonstrates the organization's commitment to providing exceptional clinical care.

12. St. Francis Physician Services, Inc. ("**SFPS**"), is a non-profit corporation organized under the laws of the State of South Carolina, with its principal place of business in South Carolina. SFPS, located in Richland County, South Carolina, provides physician and related services to residents of the State of South Carolina. In 2015 and 2016, the CDC noted a statistically significant increase in drug overdose deaths in South Carolina, and in 2017, South Carolina Governor Henry McMaster declared heroin and prescription pill addiction to be a public health emergency.

13. In 2015 and 2016, the CDC noted a statistically significant increase in drug overdose deaths in South Carolina, and in 2017, South Carolina Governor Henry McMaster declared heroin

and prescription pill addiction to be a public health emergency. SFXH, SFH, and SFPS provide health care services to South Carolina residents suffering from substance disorders and addiction.

IV. MANUFACTURER DEFENDANTS

14. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

15. **PURDUE PHARMA L.P.** is a limited partnership organized under the laws of Delaware. **PURDUE PHARMA INC.** is a New York corporation with its principal place of business in Stamford, Connecticut, and **THE PURDUE FREDERICK COMPANY** is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "**Purdue**").

16. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs.

17. **CEPHALON, INC.** ("**Cephalon, Inc.**") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

18. **TEVA PHARMACEUTICAL INDUSTRIES, LTD.** ("**Teva Ltd.**") is an Israeli corporation with its principal place of business in Petach Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. **TEVA PHARMACEUTICALS USA, INC.** ("**Teva USA**") is a Delaware corporation which is a wholly owned subsidiary of Teva Ltd. In Pennsylvania. Teva USA acquired Cephalon in October of 2011.

19. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain."[4] Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[5] In 2008, Cephalon, Inc. pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay $425 million.[6]

20. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon, Inc. products in the United States. Teva Ltd. conducts all sales and marketing

[4] *Highlights of Prescribing information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII (2009),* https://www.accessdata.fda.gov/drugsatfda docs/label/2009/020747s030lbl.pdf.
[5] *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII (2011),* https://www.accessdata.fda.gov/drugsatfda docs/label/2012/021947s015lbl.pdf.
[6] Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html.

activities for Cephalon, Inc. in the United States through Teva USA and has done so since its October of 2011 acquisition of Cephalon, Inc. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon, Inc. branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon, Inc. opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

21. All of Cephalon, Inc.'s promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.[7] Teva Ltd.'s financial reports list Cephalon, Inc.'s and Teva USA's sales as its own, and its year-end report for 2012 - the year immediately following the Cephalon, Inc. acquisition—attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon, Inc.'s specialty sales," including *inter alia* sales of Fentora®.[8] Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries, Cephalon, Inc. and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon, Inc. and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "**Cephalon**."

[7] *e.g.*, ACTIQ, http://www.actiq.com/ (displaying logo at bottom-left) (last visited Aug. 21, 2017).
[8] Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ TEVA 2012.pdf.

22. **JANSSEN PHARMACEUTICALS, INC.** is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of **JOHNSON & JOHNSON** ("**J&J**"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. **NORAMCO, INC.** is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July of 2016. **ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.**, now known as **JANSSEN PHARMACEUTICALS, INC.**, is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. **JANSSEN PHARMACEUTICA INC.**, now known as **JANSSEN PHARMACEUTICALS, INC.**, is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco, and J&J are referred to as "**Janssen**."

23. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

24. **ENDO HEALTH SOLUTIONS INC.** is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. **ENDO PHARMACEUTICALS INC.** is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its

principal place of business in Malvern, Pennsylvania. Endo Health Solutions, Inc. and Endo Pharmaceuticals Inc. are referred to as "**Endo**."

25. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

26. **ALLERGAN, PLC** is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. **ACTAVIS, PLC** acquired Allergan, PLC in March 2015, and the combined company changed its name to Allergan, PLC in January 2013. Before that, **WATSON PHARMACEUTICALS, INC.** acquired **ACTAVIS, INC.** in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis, PLC in October 2013. **WATSON LABORATORIES, INC.** is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan, PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). **ACTAVIS PHARMA, INC**. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as **WATSON PHARMA, INC. ACTAVIS, LLC** is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan, PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan, PLC exercises control over these marketing and

sales efforts and profits from the sale of Allergan, PLC/Actavis, LLC products ultimately inure to its benefit. Allergan, PLC, Actavis, PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "**Actavis**."

27. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

28. **DEPOMED, INC.** ("**Depomed**"), is an American corporation organized and existing under the laws of the State of California, with its principal place of business in Newark, California.

29. Depomed manufactures, promotes, sells, and distributes opioids, including but not limited to the branded drugs Nucynta ER, Nucynta, Gralise, Cambia, Lazanda, and Zipsor.

30. **MALLINCKRODT, PLC** is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. **MALLINCKRODT, LLC** is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, PLC. Mallinckrodt, PLC and Mallinckrodt, LLC are referred to as "**Mallinckrodt**."

31. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. Upon information and belief, in July of 2017, Mallinckrodt agreed to pay $35 million to settle allegations brought by the

Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

V. DISTRIBUTOR DEFENDANTS

32. The Distributor Defendants also are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal law. Plaintiffs allege the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing the United States.

33. **McKESSON CORPORATION** ("**McKesson**") is a Delaware corporation, with its principal place of business located in San Francisco, California. McKesson distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states.

34. **CARDINAL HEALTH, INC.** ("**Cardinal**") is an Ohio corporation with its principal place of business located in Dublin, Ohio. Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states.

35. **AMERISOURCEBERGEN DRUG CORPORATION** ("**AmerisourceBergen**") is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. AmerisourceBergen distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states.

36. Upon information and belief, **COLLEGIUM PHARMACEUTICAL, INC.** ("**Collegium**") is an American corporation organized and existing under the laws of either Delaware or Virginia, with its principal place of business in either Cumberland Rhode

Island or Canton, Massachusetts. In December of 2017, Collegium signed a definitive Commercialization Agreement with Depomed, under which Collegium commercializes the NUCYNTA pain franchise, and from which Depomed receives a royalty rate on all NUCYNTA revenues based on certain net sales thresholds.

37. **MIAMI-LUKEN, INC.** ("**Miami-Luken**") is an Ohio corporation with its principal place of business in Springboro, Ohio. Miami-Luken distributes pharmaceuticals to retail pharmaceuticals and institutional providers in Kentucky, Ohio, Tennessee, West Virginia, Pennsylvania, and Michigan.

VI. JURISDICTION AND VENUE

38. This Complaint was filed as an original action in this district.

39. Plaintiffs bring this civil action in MDL No. 2804, entitled *In Re: National Prescription Opiate Litigation.* Plaintiff is filing this Complaint directly in the Northern District of Ohio as permitted by paragraph 6(a) of this Court's April 11, 2018 Case Management Order No. 1.

40. This Court and the U.S. District Court for the District of South Carolina have subject matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, et seq. ("RICO"). This Court has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiffs' federal claims that they form part of the same case or controversy.

41. This Court has personal jurisdiction over Defendants because all the Defendants purposefully conduct substantial business in this State and in this judicial district.

42. This Court also has personal jurisdiction over all of the Defendants under 18 U.S.C. 1965(b). This Court may exercise nation-wide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiffs demonstrate national contacts. Here, the interests of justice require that Plaintiffs be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial. *See, e.g., Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F.Supp.2d 796 (1998) (citing *LaSalle National Bank v. Arroyo Office Plaza, Ltd.*, 1988 WL 23824, *3 (N.D. Ill. Mar 10, 1988); *Butcher's Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535, 539 (9th Cir. 1986)).

43. Venue is proper in this District under 28 U.S.C. § 1391(b)(2), because Plaintiffs, SFXH, SFH, and SFPS, are domiciled in this judicial district; because Plaintiff, BSHSI, by and through its affiliation with the other named Plaintiffs, is domiciled in this judicial district; and because a substantial part of the events and omissions giving rise to Plaintiffs' claims occurred in this judicial district. Furthermore, because all the Defendants are subject to personal jurisdiction in this state and in this judicial district under 28 U.S.C. § 1391(b)(1) and § (c)(2), Defendants are deemed to reside in this state and in this judicial district for the purposes of venue.

44. Further, Venue is proper in this Court pursuant to this Court's April 11, 2018 Case Management Order No. 1.

VII. FACTUAL BACKGROUND: THE OPIOID EPIDEMIC

45. The past two decades have been characterized by increasing abuse and diversion of prescription drugs, including opioid medications, in the United States.[9]

46. Prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[10]

47. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels. The News Release noted:

a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.

b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).

c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.

d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers either without a valid prescription, or for a non-medically prescribed purpose, according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.

e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.

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[9] *See* Richard C. Dart et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

[10] Katherine M. Keyes at al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52 (2014).

f. Almost 5,500 people start to misuse prescription painkillers every day.[11]

48. The number of annual opioid prescriptions written in the United States in now roughly equal to the number of adults in the population.[12]

49. Many Americans are now addicted or dependent on prescription opioids, and the number of deaths due to prescription opioid overdose has become an epidemic. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 21 percent over the 52,898 drug deaths recorded the previous year.[13]

50. Moreover, the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.[14]

51. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.[15]

52. The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain

[11] *See* Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_painkiller_overdose.html.
[12] *See* Califf et al., supra note 3.
[13] *See* Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Provisional Counts of Drug Overdose Deaths, (August 6, 2017), https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf.
[14] *See* Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015).
[15] *See* Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016).

reliever misuse and dependence. Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use, specifically among persons who report past-year dependence or abuse. The increased availability of heroin, combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose.[16]

53. Upon information and belief, and in an effort to curb the impact of opioid addiction, abuse, and/or dependency, many healthcare providers have started treating patients with Suboxone, which was once thought to be a "miracle drug" for patients suffering from opioid-related issues. However, more recent medical literature has indicated the existence of symptoms of psychosis induced by Buprenorphine, a semi-synthetic opioid which is a key component of Suboxone, in patients who have received such treatment.[17] In many instances, hospitals are then left with the uncompensated expense of providing psychiatric treatment to these patients, in an attempt to reduce the negative after-effects of their prior use of opioids, and/or their current use of Suboxone. Furthermore, because these symptoms frequently do not manifest until opioid usage has been discontinued, the costs related to the treatment of them will continue to exist moving forward.

54. The societal costs of prescription drug abuse are "huge."[18]

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[16] *See* Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016).

[17] Sannidhya Varma, MD, Srinivas Balachander, MBBS & Debasish Basu, MD, DNB, MAMS, *Buprenorphine-Induced Psychotic Symptoms: A Case Report*, [15(4)] The Primary Care Companion for CNS Disorders (2013).

[18] *See* Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 [hereinafter Brief of HDMA].

55. Across the nation, healthcare providers are struggling with a pernicious, ever-expanding epidemic of opioid addiction, dependency, and abuse. Every day, more than 90 Americans lose their lives after overdosing on opioids.[19]

56. The National Institute on Drug Abuse identifies misuse and addiction to opioids as "a serious national crisis that affects public health as well as social and economic welfare."[20] The economic burden of prescription opioid misuse alone is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.[21]

57. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999-2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.[22]

58. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.[23]

59. Every day brings a new revelation regarding the depth of the opioid plague. In one particularly jarring article, the New York Times reported in September 2017 that the

[19] Opioid Crisis, NIH, National Institute on Drug Abuse (available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis, last visited Sept. 19, 2017) ("Opioid Crisis, NIH") (citing at note 1 Rudd RA, Seth P, David F, Scholl L, Increases in Drug and Opioid- Involved Overdose Deaths — United States, 2010-2015, *MMWR MORB MORTAL WKLY REP.* 2016;65, doi:10.15585/mmwr.mm655051e1).
[20] Opioid Crisis, NIH.
[21] *Id.* (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013, *MED CARE* 2016;54(10):901-906, doi:10.1097/MLR.0000000000000625).
[22] *See* Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity & Mortality Wkly. Rep. 1445 (2016).
[23] *See* Volkow & McLellan, *supra* note 1.

epidemic, which now claims 60,000 lives a year, is now killing babies and toddlers because ubiquitous, deadly opioids are "everywhere" and mistaken as candy.[24]

60. In 2016, the President of the United States declared an opioid and heroin epidemic.[25]

61. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country.[26] Meanwhile, the manufacturers and distributors of prescription opioids extract billions of dollars of revenue from the addicted and dependent American public while billions of dollars of injury are caused by the reasonably foreseeable consequences of the prescription opioid addiction and dependency epidemic, and its ancillary effects.[27]

62. Plaintiffs incur significant uncompensated cost and expense in connection with their treatment of patients who suffer from opioid abuse, dependency, or disease. Furthermore, even in the event that the opioid epidemic is favorably resolved, Plaintiffs will continue to incur significant uncompensated cost and expense for the provision of non-opioid treatment alternatives in the future, as well as treatment to address the consequences of opioid addiction and dependency, including but not limited to the after-effects attributable to the usage of Suboxone. All of these costs and expenses are or will be directly attributable to

[24] Julie Turkewitz, 'The Pills are Everywhere': How the Opioid Crisis Claims Its Youngest Victims, N.Y. Times, Sept. 20, 2017 ("'It's a cancer,' said [grandmother of dead one-year old], of the nation's opioid problem, 'with tendrils that are going everywhere.'").

[25] *See* Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").

[26] *See* Presidential Memorandum - Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743 (Oct. 21, 2015), https://obamawhitehouse.archives.gov/the-press-office/2015/10/21/presidential-memorandum-addressing-prescription-drug-abuse-and-heroin.

[27] The Council of Economic Advisers, The Underestimated Cost of the Opioid Crisis, November 2017, https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf.

the fraudulent scheme perpetrated by Defendants in connection with their marketing, sale, and distribution of highly addictive prescription opioids.

63. Pursuant to a statutory mandate set out by the federal government under the Emergency Medical Treatment and Active Labor Act ("**EMTALA**")[28], Plaintiffs are required to provide treatment to patients suffering from opioid addiction, disease, or dependency, and/or any other opioid-related medical issues, when those patients present to Plaintiffs in an emergency condition. This treatment includes stabilization and the provision of treatment and services necessary for stabilization. Plaintiffs provide this treatment to all patients presenting in an emergency medical condition as a result of opioid use or misuse.

64. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct is causing and/or continuing to cause a national, state, and local opioid epidemic, which has created a public health emergency crisis.

VIII. THE MANUFACTURER DEFENDANTS' FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS

65. The opioid epidemic did not happen by accident.

66. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction, dependency, and other side effects, the use of opioids for chronic pain was

[28] 42 USCA § 1395dd.

discouraged or prohibited. As a result, practitioners generally did not prescribe opioids for chronic pain.

67. Each Manufacturer Defendant has conducted, and has continued to conduct, a marketing scheme designed to persuade practitioners and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted or dependent and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

68. The Manufacturer Defendants have made false and misleading claims, contrary to the language on their drugs' labels, regarding the risks of using their drugs that: (1) downplayed the serious risk of addiction and dependency; (2) created and promoted the concept of "pseudo-addiction" when signs of actual addiction and dependency began appearing and advocated that the signs of addiction and dependency should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction and dependency; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse, addiction, and dependency. The Manufacturer Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

69. The Manufacturer Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians that the Manufacturer Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded front groups, often presented in the form of continuing education.

70. Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.[29] In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors ... [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[30] This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to by prescription opioids or even non-prescription opioids, like heroin.

71. The Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

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[29] *See* Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, Fortune, Nov. 9, 2011,http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/; David Crow, *Drugmakers Hooked on $10bn Opioid Habit*, Fin. Times, Aug. 10, 2016, https://www. ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95.

[30] Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), http://turnthetiderx.org/.

a. **Each Manufacturer Defendant Used Multiple Avenues to Disseminate False and Deceptive Statements about Opioids**

72. The Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to practitioners and patients throughout the United States. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the United States, the State of South Carolina, and the Plaintiffs' Communities.

73. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that the Manufacturer Defendants' messages are accurately and consistently delivered across marketing channels - including detailing visits, speaker events, and advertising - and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

74. Upon information and belief, the Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Furthermore, it is widely known and/or believed that the Manufacturer Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

i. *Direct Marketing*

75. The Manufacturer Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Manufacturer Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, upon information and belief, the Manufacturer Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

76. Many of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for treatment of chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker, chef, and teacher, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Upon information and belief, Purdue also ran a series of ads, called "pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

77. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through "detailers" - sales representatives who visited individual practitioners and medical staff in their offices - and small-group speaker programs, often offering continuing medical education created to enhance the credibility of the programs. The Manufacturer Defendants have not corrected this misinformation. Instead, each Defendant devoted massive resources to direct sales contacts with practitioners. Upon information and belief, in 2014 alone, the

Manufacturer Defendants spent in excess of $168 million on detailing branded opioids to practitioners[31], more than twice what they spent on detailing in 2000.

78. The Manufacturer Defendants' detailing to practitioners is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, the Manufacturer Defendants purchase, manipulate and analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual practitioners, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, the Manufacturer Defendants know their detailing to practitioners is effective.

79. The Manufacturer Defendants' detailers have been reprimanded for their deceptive promotions. In March 2010, for example, the FDA found that Actavis had been distributing promotional materials that "minimize the risks associated with Kadian and misleadingly suggest that Kadian is safer than has been demonstrated." Those materials in particular "fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed."[32]

ii. *Indirect Marketing*

80. The Manufacturer Defendants' indirectly marketed their opioids using unbranded advertising, paid speakers and "key opinion leaders" ("KOLs"), and industry-funded

[31] Mike DeWine, *This Is Why I'm Suing Five Opioid Manufacturers in My State*, The Wash. Post (2017) available at https://www.washingtonpost.com/opinions/this-is-why-im-suing-five-opioid-manufacturers-in-my-state/2017/08/10/9eac79fe-7c59-11e7-a669-b400c5c7e1cc_story.html?noredirect=on&utm_term=.f18b5fc24647.

[32] Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups").

81. It is widely known and/or believed that the Manufacturer Defendants deceptively marketed opioids throughout the United States through unbranded advertising – e.g., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, the Manufacturer Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education ("CME") programs, and medical conferences and seminars. To this end, the Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

82. It is widely known and/or believed that the Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the original participating manufacturers in the tobacco litigation of the 1990s[33], the Manufacturer Defendants here used third parties that they funded, directed, and controlled to carry out and conceal their

[33] Philip Morris Inc., R. J. Reynolds, Brown & Williamson, and Lorillard.

scheme to deceive practitioners and patients about the risks and benefits of long term opioid use for chronic pain.

83. Defendants also identified practitioners to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for practitioners to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the practitioners selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

84. Borrowing a page from the "Big Tobacco" playbook, the Manufacturer Defendants worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing practitioners who served as KOLs, and (b) funding, assisting, directing, and encouraging seemingly neutral and credible Front Groups. The Manufacturer Defendants then worked together with those KOLs and Front Groups to taint the sources that practitioners and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, CME programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Manufacturer Defendants persuaded practitioners and patients that what they have long known - that opioids are addictive drugs, unsafe in most circumstances for long-term use - was untrue, and that the compassionate treatment of pain required opioids.

85. In 2007, multiple States sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion, and sale of OxyContin. Certain states settled their claims in a series of Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future. However, by using indirect marketing strategies, it is widely known and/or believed that Purdue intentionally circumvented these restrictions. Such actions include contributing to the creation of misleading publications and prescribing guidelines that lack reliable scientific basis and promote prescribing practices which have worsened the opioid crisis.

86. Pro-opioid practitioners are one of the most important avenues that the Manufacturer Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants know that practitioners rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website "In the Face of Pain" failed to disclose that practitioners who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

87. Defendants utilized many KOLs, including many of the same ones.

88. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the Manufacturer Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS")/American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by the Manufacturer Defendants.

89. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low." He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[34]

90. Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and 1990s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other practitioners promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[35] Portenoy candidly stated: "Did

[34] Good Morning America (ABC television broadcast Aug. 30, 2010).
[35] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well…I guess I did."[36]

91. In May of 2012, the Senate Finance Committee opened an investigation into financial and other connections between three opioid pharmaceutical manufacturers—Purdue Pharma, Endo Pharmaceuticals, and Johnson & Johnson—and a number of physicians, including Dr. Portenoy.[37]

92. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of American Academy of Pain Medicine ("AAPM") in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants (including nearly $2 million from Cephalon).

93. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

94. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows practitioners to manage the risk that their patients will become dependent, addicted to or abusive of opioids.

[36] *Id*.
[37] George Ochoa, *Senate Finance Committee Investigates Rise in Prescription Opioid Use*, 10 Pain Med. News (2012).

The claimed ability to pre-sort patients likely to become addicted or dependent is an important tool in giving practitioners confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into their own guidelines, indicating, also, their reliance on the Manufacturer Defendants and those under their influence and control.

95. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach practitioners throughout the United States.[38]

96. Dr. Webster also was a leading proponent of the concept of "pseudo-addiction", the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain*-a book that is still available online-when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."[39] Upon information and belief, Endo distributed this

[38] *See* Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017.

[39] Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

book to practitioners. Years later, Dr. Webster reversed himself, acknowledging that "[pseudo-addiction] obviously became too much of an excuse to give patients more medication."[40]

97. The Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the Manufacturer Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted the Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

98. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. The Manufacturer Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, the Manufacturer Defendants made sure that the Front Groups would generate only the messages that the Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members - whether patients suffering from pain or practitioners treating those patients.

99. Defendants Cephalon, Endo, Janssen, and Purdue, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described

[40] John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html.

below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), the Center for Practical Bioethics ("CPB"), the U.S. Pain Foundation ("USPF") and Pain & Policy Studies Group ("PPSG").[41]

100. The most prominent of the Manufacturer Defendants' Front Groups was the American Pain Foundation ("APF"), which, upon information and belief, received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012, primarily from Endo and Purdue. Founded in 1997, at the height of the Defendants' nefarious marketing efforts, APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction and dependency. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction, dependency, and other adverse outcomes—including death—among returning soldiers. APF also engaged in a significant multimedia campaign - through radio, television and the internet - to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach citizens of all 50 states.

101. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget

[41] *See generally, e.g.*, Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015), https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf.

for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, upon information and belief, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit.

102. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. Upon information and belief, it was often called upon to provide "patient representatives" for the Manufacturer Defendants' promotional activities, including for Purdue's "Partners Against Pain" and Janssen's "Let's Talk Pain". APF functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

103. Plaintiffs are informed, and believe, that on several occasions, representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

104. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and the Manufacturer Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the

organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[42]

105. Another front group for the Manufacturer Defendants was the American Academy of Pain Medicine ("AAPM"). With the assistance, prompting, involvement, and funding of the Manufacturer Defendants, the AAPM—founded in 1983, just as the Defendants' predatory marketing tactics were beginning to take hold—issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

106. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to practitioners. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to practitioners who attended this annual event.

107. Upon information and belief, AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored

[42] Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Ties to Pain Groups*, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel- investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

108. The Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

109. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, was taken down from AAPM's website only after a practitioner complained.[43]

110. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.[44] Treatment guidelines have been relied upon by practitioners, especially the general practitioners and family practitioners targeted by the Manufacturer Defendants. Treatment guidelines not only directly inform practitioners' prescribing practices, but are cited throughout the scientific literature and referenced by third- party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by

[43] *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997).
[44] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

Endo, Actavis, and Purdue discussed treatment guidelines with practitioners during individual sales visits.

111. At least fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.[45] One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated in the State and/or Plaintiffs' Communities during the relevant time period, are still available online, and were reprinted in the Journal of Pain. The Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Manufacturer Defendants financial support to members of the panel.

112. The Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in

[45] *Id.*

2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing.

b. The Manufacturer Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids

i. The Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair assurances grossly understating and misstating the dangerous addiction and dependency risks of opioid drugs

113. To falsely assure physicians and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction and dependency, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations - which are described below - reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted or dependent, and because those at greatest risk for addiction or dependency could be identified and managed; (2) patients who displayed signs of addiction or dependency probably were not addicted or dependent and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. The

Manufacturer Defendants have not only failed to correct these misrepresentations, they continue to make them today.

114. Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint. Yet even afterward, each Manufacturer Defendant continued to misrepresent the risks and benefits of long-term opioid use and each continues to fail to correct its past misrepresentations.

115. Some illustrative examples of the Manufacturer Defendants' false, deceptive, and unfair claims about the purportedly low risk of addiction and dependency include:

a. Actavis's predecessor caused a patient education brochure, *Managing Chronic Back Pain*, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.[46]

c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

d. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health

[46] Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

care providers who treat people with pain agree that most people do not develop an addiction problem."

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction."[47]

h. Consistent with the Manufacturer Defendants' published marketing materials, upon information and belief, detailers for Purdue, Endo, Janssen, and Cephalon minimized or omitted any discussion with practitioners of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

i. Seeking to overturn the criminal conviction of a practitioners for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.[48]

116. These claims are contrary to longstanding scientific evidence. A 2016 opioid- prescription guideline issued by the CDC (the "2016 CDC Guideline") explains that there is "[e]xtensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .)."[49] The 2016 CDC Guideline

[47] Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*], http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[48] Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

[49] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

further explains that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[50]

117. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction and dependency when it announced changes to the labels for extended-release and long-acting ("ER/LA") opioids in 2013 and for immediate release ("IR") opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed.[51]

118. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder."[52] Endo had claimed on its

[50] *Id.* at 2, 25.

[51] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf.; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Peter Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf.

[52] Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc. (*Assurance No. 15-228), at 16, https://ag.ny.gov/pdfs/Endo AOD 030116-Fully Executed.pdf.

www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in this State.

119. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, the Manufacturer Defendants also fostered a fundamental misunderstanding of the signs of addiction and dependency. Specifically, the Manufacturer Defendants misrepresented, to practitioners and patients, that warning signs and/or symptoms of addiction and dependency were, instead, signs of undertreated pain (i.e., pseudo-addiction) - and instructed practitioners to increase the opioid prescription dose for patients who were already in danger.

120. To this end, one of Purdue's employees, Dr. David Haddox, invented a phenomenon called "pseudo-addiction." KOL Dr. Portenoy popularized the term. Examples of the false, misleading, deceptive, and unfair statements regarding pseudo-addiction include:

a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one practitioner to obtain opioids, and hoarding, are all signs of pseudo-addiction, rather than true addiction.[53] The 2012 edition, which remains available for sale online, continues to teach that pseudo-addiction is real.[54]

b. Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudo-addiction . . . refers to patient behaviors that may occur when pain is under-treated… Pseudo-addiction is different from true addiction because such behaviors can be resolved with effective pain management."

[53] Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2007) at 62.
[54] *See* Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2d ed. 2012).

c. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which, upon information and belief, promoted pseudo-addiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which, upon information and belief, described pseudo-addiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

e. Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse". In a role play, a chronic pain patient with a history of drug abuse tells his practitioner that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudo-addiction, the practitioner should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The practitioner treats this patient by prescribing a high-dose, long-acting opioid.

121. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudo-addiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already addicted or dependent patients.

122. In addition to misstating the addiction and dependency risk and inventing the pseudo-addiction falsehood, a third category of false, deceptive, and unfair practice is the Manufacturer Defendants' false instructions that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction or dependency. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family practitioners who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer Defendants' misrepresentations made these practitioners feel more comfortable prescribing opioids to

their patients, and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a practitioner who became a member of Endo's speakers' bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. Purdue, upon information and belief, sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

c. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients - and not opioids - are the source of the addiction crisis and that once those "bad apples" are identified, practitioners can safely prescribe opioids without causing addiction.

123. The 2016 CDC Guideline confirms the falsity of these claims. The Guideline explains that there are no studies assessing the effectiveness of risk mitigation strategies "for improving outcomes related to overdose, addiction, abuse or misuse."[55]

124. A fourth category of deceptive messaging regarding dangerous opioids is the Manufacturer Defendants' false assurances regarding the alleged ease of eliminating opioid dependence. The Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use. In truth, the 2016 CDC Guideline explains that the symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, spontaneous abortion and premature labor in pregnant women.[56]

[55] *Id.* at 11.
[56] *Id.* at 26.

125. The Manufacturer Defendants nonetheless downplayed the severity of opioid detoxification. For example, upon information and belief, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.[57]

126. A fifth category of false, deceptive, and unfair statements the Manufacturer Defendants made to sell more drugs is that opioid dosages could be increased indefinitely without added risk. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, practitioners would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. The Manufacturer Defendants' deceptive claims include:

a. Upon information and belief, Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis appears to have continued to use these materials in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.[58] This publication is still available online.

[57] APF, *Policymaker's Guide*, *supra* note 48, at 32.
[58] APF, *Treatment Options*, *supra* note 47, at 12.

c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

d. Endo distributed a pamphlet edited by a KOL entitled Understanding Your Pain: Taking Oral Opioid Analgesics (2004 Endo Pharmaceuticals PM- 0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased… You won't 'run out' of pain relief."[59]

e. Janssen sponsored a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

f. Upon information and belief, Purdue's In the Face of Pain website promoted the notion that if a patient's practitioner does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another practitioner who would.

g. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which taught that dosage escalations are "sometimes necessary," and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages.[60]

h. In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.[61]

j. Seeking to overturn the criminal conviction of a practitioner for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an amicus brief to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.[62]

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[59] Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).
[60] APF, *Policymaker's Guide*, *supra* note 48, at 32.
[61] The College on Problems of Drug Dependence, *About the College*, http://cpdd.org (last visited Aug. 21, 2017).
[62] Brief of APF, *supra* note 49, at 9.

127. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants' representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."[63] More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."[64] The CDC also states that there is an increased risk "for opioid use disorder, respiratory depression, and death at higher dosages."[65] That is why the CDC advises practitioners to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.[66]

128. Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can cure addiction, dependency, and abuse.

129. The Manufacturer Defendants made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets "extended-release features can be compromised, causing the medication to 'dose dump,' when subject to…forms of manipulation such as cutting, grinding, or chewing, followed by

[63] 2016 CDC Guideline, *supra* note 50, at 22-23.
[64] *Id.* at 23-24.
[65] *Id.* at 21.
[66] *Id.* at 16.

swallowing."[67] Also troubling, Opana ER can be prepared for snorting using commonly available methods and "readily prepared for injection."[68] The letter discussed "the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection."[69] Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Opana ER be removed from the market.

ii. The Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair assurances grossly overstating the benefits of the opioid drugs

130. To convince practitioners and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the CDC Guideline makes clear, "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials less than 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long- term opioid use.[70] The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

131. Some illustrative examples of the Manufacturer Defendants' false claims are:

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[67] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin.,U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.
[68] *Id*. at 6.
[69] *Id*. at 21.
[70] *Id*. at 15.

a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

c. Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009) - which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

d. Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in practitioners' offices, of presumed patients in active professions; the caption read, "Pain doesn't fit into their schedules."

e. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

f. Responsible Opioid Prescribing (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.

g. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."[71] This publication is still available online.

h. Endo's NIPC website "PainKnowledge" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

[71] APF, *Treatment Options*, *supra* note 47.

i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."[72] Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

j. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the "Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

k. Purdue sponsored the development and distribution of APF's Policymaker's Guide to Understanding Pain & Its Management, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health," and "[o]verall health-related quality of life for chronic pain."[73] The Policymaker's Guide was originally published in 2011.

l. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

132. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature.

133. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[74] And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social

[72] *E.g.*, NIPC, *Persistent Pain and the Older Patient* (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20Invite.pdf.
[73] APF, *Policymaker's Guide*, *supra* note 48, at 29.
[74] Letter from Thomas Abrams to Doug Boothe, *supra* note 32.

function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

134. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs, so that practitioners and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.[75] Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also

[75] 2016 CDC Guideline, *supra* note 50, at 12.

makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

135. Purdue's competitors were aware of this problem. For example, upon information and belief, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Upon information and belief, Purdue's sales representatives continue to tell practitioners that OxyContin lasts a full 12 hours.

136. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

> OxyContin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, OxyContin has been a miracle medication.[76]

137. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids.

[76] Reply Brief of Amicus Curiae of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, *Howland v. Purdue Pharma L.P.*, No. 2003-1538 (Ohio Apr. 13, 2004), 2004 WL 1637768, at *4 (footnote omitted).

Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.[77] Specifically, the FDA advised that Fentora "is only approved for breakthrough cancer pain in patients who are *opioid-tolerant,* meaning those patients who take a regular, daily, around-the-clock narcoticpain medication."[78]

138. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, and for which it is not safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give practitioners the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. Forexample:

a. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain,* published in a supplement of Pain Medicine News in 2009. The CME instructed practitioners that "[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.

b. Upon information and belief, Cephalon's sales representatives set up hundreds of speaker programs for practitioners, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

[77] *See* U.S. Food & Drug Admin., *Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007), https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm05 1273.htm.
[78] *Id.*

c. In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News - three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" - and not just cancer pain.

139. Cephalon's deceptive marketing gave practitioners and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

140. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of practitioners suspected of inappropriately prescribing its drugs. Rather than report these practitioners to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin - the same OxyContin that Purdue had promoted as less addictive - in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action - even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described it internally as "an organized drug

ring" until years after law enforcement shut it down. In doing so, Purdue protected its own profits at the expense of public health and safety.[79]

141. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

c. The Manufacturer Defendants made Materially Deceptive Statements and Concealed Materials Facts

142. As alleged herein, the Manufacturer Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids. The Manufacturer Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

143. Defendant Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the

[79] Harriet Ryan et al., *More Than 1 Million Oxycontin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, http://www.latimes.com/projects/la-me- oxycontin-part2/.

evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Disseminating misleading statements concealing the true risk of addiction and dependency, and promoting the deceptive concept of pseudo-addiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

d. Distributing brochures to practitioners, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudo-addiction, even for high-risk patients;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose- dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOL practitioners who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction and dependency;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non- cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known

rates of abuse, dependency, and addiction and the lack of validation for long-term efficacy;

n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction and dependency in this population;

p. Exclusively disseminating misleading statements in education materials to medical facility practitioners and staff while purportedly educating them on new pain standards;

q. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing; and

r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these practitioners by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

144. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;

d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

e. Disseminating misleading statements concealing the true risk of addiction and dependency, and promoting the misleading concept of pseudo-addiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations - including over $5 million to the organization responsible for many of the most egregious misrepresentations - that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction and dependency in this population;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non- cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudo-addiction;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse, dependency, and addiction and the lack of validation for long-term efficacy; and

n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

145. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non- cancer pain and that opioids improve quality of life, while concealing contrary data;

c. Disseminating deceptive statements concealing the true risk of addiction and dependency, and promoting the deceptive concept of pseudo-addiction through internet sites over which Janssen exercised final editorial control and approval;

d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long- term and dose dependent risks of opioids versus NSAIDs;

f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction and dependency in this population;

i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and dependency, and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudo-addiction;

l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non- cancer pain, including known rates of abuse, dependency, and addiction and the lack of validation for long-term efficacy;

m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

146. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudo-addiction, even for high-risk patients;

c. Providing significant financial support to pro-opioid KOL practitioners who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non- cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of practitioners, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

147. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

c. Creating and disseminating advertisements that concealed the risk of addiction and dependency in the long-term treatment of chronic, non-cancer pain; and

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

d. The Manufacturer Defendants Fraudulently Concealed Their Misconduct

148. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The

history of opioids, as well as research and clinical experience establish that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes. The FDA warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction and dependency, hospitalization, and death – all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction and dependency, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

149. At all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies

that were not, and have not yet become, public. For example, PainKnowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own role.

150. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented "pseudo-addiction" and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction and dependency. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales.

IX. THE DISTRIBUTOR DEFENDANTS' UNLAWFUL DISTRIBUTION OF OPIOIDS

151. The Distributor Defendants owe a duty under federal law (21 U.S.C. § 823, 21 CFR 1301.74) to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted.

152. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

153. Each Distributor Defendant repeatedly and purposefully breached its duties under state and federal law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes.

154. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, dependency, morbidity and mortality.

155. The Distributor Defendants' intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid epidemic and causing the damages alleged herein.

a. **The Distributor Defendants have a Duty under Federal Law to Guard Against and Report Unlawful Diversion, and to Report and Prevent Suspicious Orders**

156. Opioids are a controlled substance. These "Schedule II" drugs are controlled substances with a "high potential for abuse." 21 U.S.C. §§ 812(b), 812(2)(A)-(C).

157. Each Distributor Defendant was required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

158. Each Distributor Defendant has an affirmative duty under federal law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1).

159. Federal regulations impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

160. "Suspicious orders" include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. *See* 21 CFR 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

161. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug*

Enforcement Administration, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported.

162. These prescription drugs are regulated for the purpose of providing a "closed" system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[80]

163. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities.[81]

164. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly…distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as…the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[82]

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[80] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

[81] Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)-now known as the Healthcare Distribution Alliance (HDA)-is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, *About*, https://www.healthcaredistribution.org/about (last visited Aug. 21, 2017). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, https://www.nacds.org/ about/mission/ (last visited Aug. 21, 2017).

[82] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute

165. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.[83]

166. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[84] The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."[85] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

167. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.[86] This letter reminds the Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[87] The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement

controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), *filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

[83] *See* Brief for HDMA and NACDS, *supra* note 85, 2016 WL 1321983, at *4 ("[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

[84] Rannazzisi Letter, *supra* note 83, at 2.

[85] *Id.* at 1.

[86] *Id.* at 2.

[87] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv- 00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other

> than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[88]

Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[89]

168. The Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

169. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to

[88] *Id.*
[89] *Id.*

which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[90]

170. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers from which Defendants knew prescription opioids were likely to be diverted.

171. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

172. Each Distributor Defendant owes a duty under federal law to investigate and refuse suspicious orders of prescription opioids.

173. Each Distributor Defendant owes a duty under federal law to report suspicious orders of prescription opioids.

174. Each Distributor Defendant owes a duty under federal law to prevent the diversion of prescription opioids into illicit markets throughout the United States.

175. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction and dependency.

176. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, dependency, morbidity and mortality and the damages caused thereby.

b. The Distributor Defendants Breached their Duties

177. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from

[90] *See* Brief of HDMA, *supra* note 19, 2012 WL 1637016, at *2.

legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.[91]

178. The sheer volume of prescription opioids distributed to pharmacies in various areas, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted, was excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[92]

179. The Distributor Defendants failed to report "suspicious orders," or which the Distributor Defendants knew were likely to be diverted, to the federal authorities, including the DEA.

180. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

181. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

182. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.[93]

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[91] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

[92] *See* Rannazzisi Decl., r 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

[93] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,322 (2012)).

183. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal law.

184. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.[94]

185. On May 8, 2018, the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations held a hearing entitled "Combating the Opioid Epidemic: Examining Concerns about Distribution and Diversion". During this Hearing the House Committee heard testimony from representatives of some of the Distributor Defendants. Dr. Joseph Mastandrea, Chairman of the Board for the Defendant Miami-Luken, admitted that his Company contributed to the opioid epidemic and that the Company had past failings in maintaining effective controls to prevent the diversion of opioids.

186. The federal laws at issue here are public safety laws.

187. The Distributor Defendants' violations of public safety statutes constitute prima facie evidence of negligence under State law.

188. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by federal law which are required to legally acquire and maintain a license to distribute prescription opiates.

[94] *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

189. The Distributor Defendants acted with actual malice in breaching their duties, *i.e.*, they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

190. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

c. The Distributor Defendants Have Sought to Avoid and Have Misrepresented their Compliance with their Legal Duties

191. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under federal law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with legal duties.

192. Distributor Defendants have refused to recognize any duty beyond reporting suspicious orders. In *Masters Pharmaceuticals*, the HDMA, a trade association run by the Distributor Defendants, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

a. The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to investigate orders (e.g., by interrogating pharmacies and physicians) and take action to halt suspicious orders before they are filled."[95]

b. The Associations argued that, "DEA now appears to have changed its position to require that distributors not only report suspicious orders, but investigate and halt suspicious orders. Such a change in agency position must be accompanied by an

[95] Brief for HDMA and NACDS, *supra* note 85, 2016 WL 1321983, at *4-5.

acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it is changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications."[96]

c. The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious."[97]

d. The Association complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties."[98]

e. The Associations alleged (inaccurately) that "DEA's regulations… sensibly impose… a duty on distributors simply to report suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders."[99]

f. The Associations also inaccurately argued that, "[i]mposing a duty on distributors - which lack the patient information and the necessary medical expertise - to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands."[100]

193. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.[101]

194. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical's license and determined that

[96] *Id.* at *8 (citations and quotation marks omitted).
[97] *Id.* at *14.
[98] *Id.* at *22.
[99] *Id.* at *24-25.
[100] *Id.* at *26.
[101] *See* Brief of HDMA, *supra* note 19, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and-if it is able to determine that the order is not likely to be diverted into illegal channels-ship the order." *Id*. at 212. Master Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 218-19, 226. A distributor's investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. *Id*. at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id*. at 220.

195. Wholesale Distributor McKesson has recently been forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[102] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes

[102] *See* Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), https://www.justice.gov/opa/press- release/file/928476/download.

by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[103] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq*., at the McKesson Distribution Centers."

196. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.[104] In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed to do so.[105] The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."[106] As a result of these violations, McKesson was fined and required to pay to the United States $150,000,000.[107]

197. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those

[103] *Id*. at 4.
[104] *Id*. at 4.
[105] *Id*.
[106] *Id*.; *see also* Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter 2017 Settlement Agreement and Release] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), https://www.justice.gov/opa/press-release/file/928471/download.
[107] *See* 2017 Settlement Agreement and Release, *supra* note 112, at 6.

obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

198. Because of the Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.[108] The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[109] These actions include the following:

a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

[108] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.
[109] *Id.*

e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

199. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp

drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[110]

200. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

201. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[111] Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results.

202. Similarly, Defendant McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply

[110] *See* Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6,2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had No Leadership" in W Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills.

[111] Lenny Bernstein et al., How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job," Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7- 7b6c1998b7a0_story.html.

passionate about curbing the opioid epidemic in our country."[112] Again, given McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

203. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiffs now assert.

204. Meanwhile, the opioid epidemic rages unabated in the State of South Carolina, and in the United States as a whole.

205. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

206. The wrongful actions and omissions of the Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiffs' racketeering allegations below.

207. The Distributor Defendants have abandoned their duties imposed under federal law, taken advantage of a lack of DEA law enforcement, and abused the privilege of distributing controlled substances.

[112] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials- switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

X. THE MANUFACTURER DEFENDANTS' UNLAWFUL FAILURE TO PREVENT DIVERSION, AND TO MONITOR, REPORT, AND PREVENT SUSPICIOUS ORDERS

208. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under federal law.

209. Like the Distributor Defendants, the Manufacturer Defendants were required to register with the DEA to manufacture schedule II controlled substances, like prescription opioids. *See* 21 U.S.C. § 823(a). A requirement of such registration is the:

> Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes…

21 USCA § 823(a)(1).

210. Additionally, as "registrants" under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74. *See also* 21 C.F.R. § 1301.02 ("Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21 C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act [21 U.S.C. 823 or 958]").

Like the Distributor Defendants, the Manufacture Defendants breached these duties.

211. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew - just as the Distributor Defendants knew - the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

212. Federal statutes and regulations are clear: just like opioid distributors, opioid manufacturers are required to "design and operate a system to disclose… suspicious orders of controlled substances" and to maintain "effective controls against diversion." 21 C.F.R. § 1301.74; 21 USCA § 823(a)(1).

213. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[113]

[113] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

214. In the press release accompanying the settlement, the Department of Justice stated: Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone… Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street…" Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . ."[114]

215. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances - orders that are unusual in their frequency, size, or other patterns… [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[115]

216. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[116]

217. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

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[114] *Id.*
[115] *Id.*
[116] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt MOA").

> With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:
>
> i. conduct adequate due diligence of its customers;
>
> ii. detect and report to the DEA orders of unusual size and frequency;
>
> iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
>
> > 1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
> >
> > 2. orders that purchased a disproportionate amount of substance which is most often abused compared to other products, and
> >
> > 3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallickrodt was aware;
>
> iv. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and
>
> v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[117]

218. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt

[117] 2017 Mallinckrodt MOA at p. 2-3.

further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and would "design and operate a system that meets the requirements of 21 CFR 1301.74(b)… [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[118]

219. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to "downstream" registrants." Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[119]

220. The same duties imposed by federal law on Mallinckrodt were imposed upon all Distributor Defendants.

221. The same business practices utilized by Mallinckrodt regarding "charge backs" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other DistributorDefendants.

222. Through, *inter alia*, the charge back data, the Manufacturer Defendants could monitor suspicious orders of opioids.

[118] *Id.* at 3-4.
[119] *Id.* at p.5.

223. The Manufacturer Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal law.

224. The Manufacturer Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

225. The Manufacturer Defendants have misrepresented their compliance with federal law.

226. The wrongful actions and omissions of the Manufacturer Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiffs' racketeering allegations below.

227. The Manufacturer Defendants' actions and omissions in failing to effective prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids throughout the United States.

XI. DEFENDANTS' UNLAWFUL CONDUCT, VIOLATION OF STATE AND FEDERAL STATUTES AND REGULATIONS, AND BREACH OF LEGAL DUTIES, CAUSED THE HARM ALLEGED HEREIN, RESULTING IN SUBSTANTIAL DAMAGES TO PLAINTIFFS

228. As the Manufacturer Defendants' efforts to expand the market for opioids increased so have the rates of prescription and sale of their products — and the rates of opioid-related substance abuse, hospitalization, and death among the people of the United States. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids.

229. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[120]

230. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths, dependencies, and addictions.[121]

231. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[122]

232. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.[123]

233. As shown above, the opioid epidemic has escalated with devastating effects: substantial opioid-related substance abuse, hospitalization and death that mirrors Defendants' increased distribution of opioids.

234. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, like heroin, the massive distribution of opioids by Defendants has caused the Defendant-caused opioid epidemic to include heroin addiction, abuse, and death.

235. Defendants repeatedly and purposefully breached their duties under federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes.

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[120] *See* Dart at al., *supra* note 11.
[121] *See* Volkow & McLellan, *supra* note 1.
[122] *See* Califf et al., *supra* note 3.
[123] *See* Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *supra* note 13.

236. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, dependency, addiction, morbidity and mortality in the United States. This diversion and the epidemic are direct causes of foreseeable harms to the Plaintiffs.

237. Defendants' unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiffs seek relief, as alleged herein.

XII. FACTS PERTAINING TO THE NAMED PLAINTIFFS

238. Plaintiffs have treated and continue to treat numerous patients for opioid-related conditions and complications, including but not limited to: (1) opioid overdose; (2) opioid detoxification; (3) opioid addiction, disease, and/or dependency; (4) medical conditions complications caused by opioid use; (5) treatment for children born with opioid addictions—which consists of intensive, complex, and lengthy treatment—because their mothers were opioid addicts; (6) treatment for children whose medical conditions and complications may be caused or exacerbated by the use of opioids by other individuals; and (7) psychiatric and/or related behavioral health treatment for opioid users who participate in behavioral health treatment programs, for which treatment is intensive, complex, and lengthy.

239. Additionally, opioid users present themselves to Plaintiffs claiming to have illnesses and medical problems, which are actually pretexts for obtaining opioids to satisfy cravings, prevent withdrawal symptoms, and/or for recreational use. Plaintiffs incur operational costs, consisting of expending resources and incurring expenses in diagnosing, testing, and otherwise dealing with individuals seeking opioids without a valid or legitimate prescription, before their true status can be determined and they can be rejected as patients.

240. Hospitals also incur operational costs in the form of surgical procedures and medical treatment that is more complex and expensive than would otherwise be the case if patients were not suffering opioid conditions which complicates surgical procedures and requires additional measures and treatments. Because opioid users often present to Plaintiffs in an emergency medical condition, they require intensive treatment services to stabilize medical conditions caused or exacerbated by opioid use or misuse.

241. Collectively, the patients described above will be referred to herein as "patients with opioid conditions."

242. These patients' opioid conditions are the direct and proximate results of the opioid epidemic created and engineered by Defendants.

243. Hospitals also incur operational costs related to treating patients, including children, whose medical conditions and complications may be caused by or exacerbated by others' use of opioids.

244. Hospitals incur operational costs in the form of providing additional treatments and services, including but not necessarily limited to, therapeutic and prescription drug purchases for patients with opioid conditions who have other medical conditions that must be treated.

245. Hospitals incur operational costs related to the provision of laboratory and other diagnostic testing for the treatment and/or management of patients with opioid conditions, including those undergoing therapeutic interventions to address opioid use or misuse.

246. Hospitals incur operational costs relating to treatment with life support-related healthcare services to prevent death in certain instances of opioid overdose, including but not limited to treatment for babies born with addictions and dependencies.

247. Due to the high prevalence of individuals suffering from opioid-related addiction, disease, or dependency and needing medical care, hospitals incur increased operational costs related to providing the necessary screening procedures for the acceptance of patients, monitoring patients, monitoring and credentialing healthcare providers, providing additional security to address public safety concerns, (particularly in the emergency department), storing and safeguarding controlled substances, adding regulatory compliance, increasing litigation defense costs, procuring and maintaining insurance, diverting assets and employees from the provision of other needed healthcare, and increasing human resource costs.

248. Hospitals incur lost revenue and lost opportunity costs attributable to the required discharge of patients who are diverting and/or using opioids in a manner that does not comply with prescribed use.

249. Hospitals incur operational costs related to researching non-opioid treatment alternatives and training staff accordingly.

250. Plaintiffs each have a price list, which sets the prices for a comprehensive listing of items billable to patients or the patients' health insurance provider for services received.

251. These price lists generally include the full charges for the health services rendered. The full charges are only partially reimbursed by private health insurers, Medicare, Medicaid and other payors. Plaintiffs have provider agreements with private health insurers whereby they accept payment from the health insurers at a discounted rate on behalf of insured patients and often do not cover the cost of providing care to patients. The difference between the full charges and the discounted rate is lost to the hospitals. Medicare and Medicaid establish set rates for services that are less than the hospitals' full charges and costs, and the difference between the set rates and the full charges is lost to the hospitals.

252. Plaintiffs bill their charges to uninsured patients. Typically, where there is no health insurance, Medicare, or Medicaid coverage, these charges are not reimbursed and are lost to hospitals. Plaintiffs also provide financial assistance to patients, and receive only a portion of the charges and/or costs associated with providing services to these patients.

253. Hospitals incur partial monetary losses for patients with health insurance, and total monetary losses for uninsured patients, for the treatment of patients with opioid conditions. These patients would not have presented to Plaintiffs and would not have had opioid conditions, but for the opioid epidemic created and engineered by Defendants. Accordingly, Plaintiffs' aforesaid monetary losses are the direct and proximate result of Defendants' acts and omissions previously specified herein.

254. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the opioid epidemic would result in a corresponding epidemic of patients with opioid conditions presenting for treatment at hospitals, hospital outpatient clinics, and/or other hospital facilities. It was also foreseeable to Defendants that Plaintiffs would suffer the aforesaid monetary losses because of the opioid epidemic, since hospitals typically are not reimbursed for their treatment of uninsured patients, receive only partial reimbursement for their treatment of patients with health insurance, and provide services that cost more than the corresponding payment rates set by Medicare, Medicaid, and other third-party payors.

XIII. CAUSES OF ACTION

COUNT I – RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT 18 U.S.C. 1961, *et seq*. (Against All Defendants)

255. Plaintiffs reallege and incorporate by reference all preceding paragraphs.

256. Plaintiffs bring this Count against each of the Defendants, as described above.

257. The Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

258. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c); *United State v. Turkette*, 452 U.S. 576, 580 (1981).

259. The term "enterprise" is defined as including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. U.S.*, 556 U.S. 938, 944 (2009). The definition of "enterprise" in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section "describes two separate categories of associations that come within the purview of an 'enterprise' -- the first encompassing organizations such as corporations, partnerships, and other 'legal entities,' and the second covering 'any union or group of individuals associated in fact although not a legal entity.'" *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. *Id*.

260. For over a decade, the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and

surreptitiously increasing the volume of opioids they sold. However, the Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the Defendants operated and continue to operate within the "closed-system" created under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the "CSA"). The CSA restricts the Defendants' ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

261. The closed-system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from "legitimate channels of trade" to the illicit market by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances]."[124]

262. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.[125] As discussed in

[124] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).
[125] 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

detail below, through the Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA.[126] In doing so, Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate obscene profits.

263. Defendants' illegal scheme was hatched by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed in perfect harmony by each of them. In particular, each of the Defendants were associated with, and conducted or participated in, the affairs of the RICO enterprise (defined below and referred to collectively as the "Opioid Diversion Enterprise"), whose purpose was to engage in the unlawful sales of opioids, and deceive the public and federal and state regulators into believing that the Defendants were faithfully fulfilling their statutory obligations. The Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted and dependent American public, while entities like the Plaintiffs experienced billions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction and dependency epidemic. As explained in detail below, the Defendants' misconduct violated Section 1962(c) and Plaintiffs are entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

[126] 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

264. Alternatively, the Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA")[127] is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

265. On information and belief, each of the Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

266. Each of the Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and manufacturers beyond the Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

267. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the "Opioid Diversion Enterprise."

[127] Health Distribution Alliance, History, Health Distribution Alliance, (last accessed on September 15, 2017), https://www.healthcaredistribution.org/about/hda-history.

a. The Opioid Diversion Enterprise

268. Recognizing that there is a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970.[128] The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals.[129] Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.[130] As reflected in comments from United States Senators during deliberation on the CSA, the "[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls."[131] Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market."[132] Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.[133] All registrants -- manufacturers and distributors alike -- must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion.[134] When registrants at any level fail to

[128] Joseph T. Rannazzisi Decl., r 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).
[129] *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.
[130] *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20; 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).
[131] *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan 23, 1970).
[132] See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).
[133] See Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012 (available at https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea- rannazzisi.pdf).
[134] *Id.*

fulfill their obligations, the necessary checks and balances collapse.[135] The result is the scourge of addiction and dependency that has occurred.

269. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, design and operate a system to disclose suspicious orders, and to inform the DEA of any suspicious orders.[136] The DEA also published suggested questions that a distributor should ask prior to shipping controlled substances, in order to "know their customers."[137]

270. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs."[138] When evaluating production quotas, the DEA was instructed to consider the following information:

a. Information provided by the Department of Health and Human Services;

b. Total net disposal of the basic class by all manufacturers;

c. Trends in the national rate of disposal of the basic class;

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[135] Joseph T. Rannazzisi Decl. ,r 10, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

[136] Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (September 27, 2006); Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (December 27, 2007).

[137] Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf).

[138] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

d. An applicant's production cycle and current inventory position;

e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and

f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.[139]

271. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.[140]

272. At all relevant times, the Defendants operated as an association-in- fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their statutory duty to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

273. The opioid epidemic has its origins in the mid-1990s, during which per capita purchases of methadone, hydrocodone, and oxycodone increased 13-fold, 4-fold, and 9-fold, respectively, between 1997 and 2007. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the county with a dose of 5 milligrams of

[139] See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015
(available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf). *Id.* (citing 21 U.S.C. 842(b)).
[140] *Id.* (citing 21 U.S.C. 842(b)).

hydrocodone every 4 hours for 1 month.[141] On information and belief, the Opioid Diversion Enterprise has been ongoing for at least the last decade.[142]

274. The Opioid Diversion Enterprise was and is a shockingly successful endeavor. It Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis. But, it was not until recently that United States and State regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public.

275. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each Defendant; (b) was separate and distinct from the pattern of racketeering in which the Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Defendants; (d) characterized by interpersonal relationships among the Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. *Turkette*, 452 U.S. at 580; *Boyle*, 556 U.S. at 944 (2009). Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the Defendants would have a larger pool of prescription opioids from which to profit.

[141] Keyes KM, Cerda M, Brady JE, Havens JR, Galea S. Understanding the rural-urban differences in nonmedical prescription opioid use and abuse in the United States. Am J Public Health. 2014;104(2): e52- 9.

[142] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid- drug-epidemic.

276. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum (described in greater detail below) and the Healthcare Distribution Alliance lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations[143] The HDA and other members of the Pain Care Forum contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees and political parties. Plaintiffs are informed and believe that the Pain Care Forum and their members poured at least $3.5 million into lobbying efforts in this jurisdiction while the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

277. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the

[143] See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now- healthcare-distribution- alliance/; Lenny Bernstein & Scott Higham, Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea- slowed-enforcement-while-the-opioid-epidemic- grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13- d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, Investigation: U.S. Senator Calls for Investigation of DEA, Enforcement Slowdown Amid Opioid Crisis, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement- slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of- pain-pills-.

identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

278. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the County and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

279. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

280. Each of the Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the

Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting, requirements, and financial statements.

281. The Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum, the HDA, and through their contractual relationships.

282. The Pain Care Forum ("PCF") has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

283. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[144] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[145]

284. Not surprisingly, each of the Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.[146] In 2012, membership and participating organizations included the HDA (of which all Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for Janssen

[144] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.),https://www.publicintegrity.org/2016/09/19/20201/pro- painkiller-echo- chamber-shaped-policy-amid-drug-epidemic (emphasis added).
[145] *Id*.
[146] PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule- amp.pdf

Pharmaceuticals), Actavis (*i.e.*, Allergan), and Teva (the parent company of Cephalon).[147] Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.[148] Plaintiffs are informed and believe that the Distributor Defendants participated directly in the PCF as well.

285. The 2012 Meeting Schedule for the Pain Care Forum is particularly revealing on the subject of the Defendants' interpersonal relationships. The meeting schedule indicates that meetings were held at a central location in Washington, D.C., on a monthly basis, unless otherwise noted. Local members were "encouraged to attend in person" at the monthly meetings. And, the meeting schedule indicates that the quarterly and year-end meetings included a "Guest Speaker."

286. The 2012 Pain Care Forum Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drug makers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

287. Second, the HDA -- or Healthcare Distribution Alliance -- led to the formation of interpersonal relationships and an organization between the Defendants. Although the

[147] *Id*. Plaintiff is informed and believes that Mallinckrodt became an active member of the PCF sometime after 2012.
[148] *Id*. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. Executive Committee, Healthcare Distribution Alliance (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/executive-committee.

entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis (*i.e.*, Allergan), Endo, Purdue, Mallinckrodt and Cephalon were members of the HDA.[149] And, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

288. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[150] Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Defendants.

289. The application for a manufacturer membership in the HDA further indicates the level of connection that existed between the Defendants.[151] The manufacturer membership application must be signed by a "senior company executive," and it requests that he

[149] Manufacturer Membership, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/membership/manufacturer.
[150] Manufacturer Membership Benefits, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/-/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en.
[151] Manufacturer Membership Application, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/-/media/pdfs/membership/manufacturer-membership-application.ashx?la=en.

manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.[152]

290. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."[153]

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.[154]

c. Health, Beauty and Wellness Committee: "This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain." Participation in this committee includes distributors and manufacturer members.[155]

d. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.[156]

e. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative

[152] *Id.*
[153] *Id.*
[154] *Id.*
[155] *Id.*
[156] *Id.*

and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.[157]

f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[158]

g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[159]

h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.[160]

291. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation includes Distributor and Manufacturer Members.[161]

292. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise's organization.

293. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA, and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers… to hold strategic business discussions on the most

[157] *Id.*
[158] *Id.*
[159] *Id.*
[160] *Id.*
[161] *Id.*

pressing industry issues."[162] The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[163] The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. And, it is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.[164]

294. Third, the Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

295. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids.[165] As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales.[166] On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing

[162] Business and Leadership Conference - Information for Manufacturers, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers.
[163] *Id.*
[164] 2015 Distribution Management Conference and Expo, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/events/2015-distribution-management- conference.
[165] Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea- mallinckrodt/?utm_term=.b24cc81cc356; see also, Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png; Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid- investigation-letter-manufacturers.png; Letters From Sen. Claire McCaskill, (March 28, 2017), https://www.mccaskill.senate.gov/opioid- investigation; Purdue Managed Markets, Purdue Pharma, (accessed on September 14, 2017), http://www.purduepharma.com/payers/managed-markets/.
[166] *Id.*

relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.[167] The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

296. The contractual relationships among the Defendants also include vault security programs. The Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Plaintiffs are informed and believe that manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. Plaintiffs are informed and believe that these agreements were used by the Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

297. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription

[167] Webinars, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/resources/webinar-leveraging-edi.

opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants was in communication and cooperation.

298. According to articles published by the Center for Public Integrity and The Associated Press, the Pain Care Forum -- whose members include the Manufacturers and the Distributors' trade association has been lobbying on behalf of the Manufacturers and Distributors for "more than a decade."[168] And, from 2006 to 2016 the Distributors and Manufacturers worked together through the Pain Care Forum to spend over $740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures.[169] Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000, if not longer.[170]

299. As described above, the Defendants began working together as early as 2006 through the Pain Care Forum and/or the HDA to promote the common purpose of their enterprise. Plaintiffs are informed and believe that the Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

b. Conduct of the Opioid Diversion Enterprise

300. During the time period alleged in this Complaint, the Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report

[168] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo- chamber-shaped-policy-amid- drug-epidemic.
[169] *Id.*
[170] HDA History, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/hda-history.

suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits, as follows:

301. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

302. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

303. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

304. Defendants paid nearly $800 million dollars to influence local, state and federal governments through joint lobbying efforts as part of the Pain Care Forum. The Defendants were all members of their Pain Care Forum either directly or indirectly through the HDA. The lobbying efforts of the Pain Care Forum and its members, included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

305. The Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

306. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied

Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[171]

307. The Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Plaintiffs are informed and believe that the Manufacturer Defendants used the chargeback program to acquire detailed high-level data regarding sales of the opioids they manufactured. And, Plaintiffs are informed and believe that the Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

308. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the Defendants.

309. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely

[171] *See* HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea- slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13- d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of- pain-pills-.

to divert prescription opioids.[172] On information and belief, the "know your customer" questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

310. The Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[173] and 117 recommended decision in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders -- all for failure to report suspicious orders.[174]

311. Defendants' scheme had decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the State and Federal Government's response to the manufacture and distribution of prescription opioids by increasing production quotas

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[172] Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. Pharmaceutical Production Diversion: Beyond the PDMA, Purdue Pharma and McQuite Woods LLC, (available at https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

[173] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

[174] *Id.*

through a systematic refusal to maintain effective controls against diversion, and identify suspicious orders and report them to the DEA.

312. The Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was pro- opioid. The Manufacturer and Distributor Defendants did this through their participation in the Pain Care Forum and Healthcare Distributors Alliance.

313. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the Defendants ensured that the DEA had no basis for refusing to increase or decrease the production quotas for prescription opioids due to diversion of suspicious orders. The Defendants influenced the DEA production quotas in the following ways:

a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the Pain Care Forum;

b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;

c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;

d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;

e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing opioids."[175]

[175] Harriet Ryan, et al., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/

f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

h. The Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders;

i. The Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA; and

j. The Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

314. The scheme devised and implemented by the Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

c. Pattern of Racketeering Activity

315. The Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); and 18 § 1961(D) by the felonious manufacture, importation, receiving, concealment buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

i. *The Defendants Engaged in Mail and Wire Fraud*

316. The Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

317. The Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

318. The Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

319. In devising and executing the illegal scheme, the Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

320. The Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, and misrepresentations, promises, and omissions.

321. The Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of the Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;

c. Defendants' DEA registrations;

d. Documents and communications that supported and/or facilitated Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Manufacturers;

k. Rebates and chargebacks from the Manufacturers to the Distributors;

l. Payments to Defendants' lobbyists through the Pain Care Forum;

m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

322. On information and belief, the Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

323. Purdue manufactures multiple forms of prescription opioids, including but not limited to: OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. Purdue manufactured and shipped these prescription opioids to the Distributor Defendants.

324. The Distributor Defendants shipped Purdue's prescription opioids throughout the United States.

325. Cephalon manufactures multiple forms of prescription opioids, including but not limited to: Actiq and Fentora. Cephalon manufactured and shipped these prescription opioids to the Distributor Defendants.

326. The Distributor Defendants shipped Teva's prescription opioids throughout the United States.

327. Janssen manufactures prescription opioids known as Duragesic. Janssen manufactured and shipped its prescription opioids to the Distributor Defendants.

328. The Distributor Defendants shipped Janssen's prescription opioids throughout the United States.

329. Endo manufactures multiple forms of prescription opioids, including but not limited to: Opana/Opana ER, Percodan, Percocet, and Zydone. Endo manufactured and shipped its prescription opioids to the Distributor Defendants.

330. The Distributor Defendants shipped Janssen's prescription opioids throughout the United States.

331. Actavis manufactures multiple forms of prescription opioids, including but not limited to: Kadin and Norco, as well as generic versions of the drugs known as Kadian, Duragesic and Opana. Actavis manufactured and shipped its prescription opioids to the Distributor Defendants.

332. The Distributor Defendants shipped Actavis' prescription opioids throughout the United States.

333. Mallinckrodt manufactures multiple forms of prescription opioids, including but not limited to: Exalgo and Roxicodone.

334. The Distributor Defendants shipped Mallinckrodt's prescription opioids throughout the United States.

335. The Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

336. At the same time, the Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

337. Plaintiffs are also informed and believe that the Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

338. The Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

339. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report

suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

340. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. But, Plaintiffs have described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

341. The Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the Defendants.

342. The Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

343. The Defendants hid from the general public, and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the Defendants were filling on a daily basis—leading to the diversion of millions of doses of prescription opioids into the illicit market.

344. The Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

345. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

346. As described herein, the Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

347. The predicate acts all had the purpose of generating significant revenue and profits for the Defendants while Plaintiffs were left with substantial monetary losses through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

348. The pattern of racketeering activity alleged herein and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

349. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future.

350. Many of the precise dates of the Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an

essential part of the successful operation of the Opioids Addiction and Opioid Diversion Enterprise alleged herein depended upon secrecy.

351. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including the Plaintiffs. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on consumers and/or the Plaintiffs. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products.

352. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

353. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiffs as set out herein, by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

354. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

ii. *The Defendants Manufactured, Sold, and/or Dealt in Controlled Substances and their Crimes are Punishable as Felonies*

355. The Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

356. The Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

357. Each of the Defendants qualify as registrants under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances., and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

358. Pursuant to the CSA and the Code of Federal Regulations, the Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

359. As is indicated by government documents, and described in more detail below, the Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

360. For example, The DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay $150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.[176]

361. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles yet failed to alert the DEA.[177] The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles,

[176] McKesson, McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims, About McKesson / Newsroom / Press Releases, (January 17, 2017), http://www.mckesson.com/about-mckesson/newsroom/press- releases/2017/mckesson-finalizes-settlement-with-doj-and-dea-to-resolve-past-claims/.

[177] Harriet Ryan, et al., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.

including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring."[178] Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."[179]

362. Finally, Mallinckrodt was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012.[180] After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a $35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt's response was that everyone knew what was going on in Florida but they had no duty to report it.[181]

363. Plaintiffs are informed and believe that the foregoing examples reflect the Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. This conclusion is

[178] *Id.*
[179] *Id.*
[180] Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356. This number accounted for 66% of all oxycodone sold in the state of Florida during that time.
[181] *Id.*

supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants.[182] For example:

364. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

365. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

366. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

367. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

368. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

[182] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

369. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

370. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

371. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

372. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

373. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD,

La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

374. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

375. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future.

376. Many of the precise dates of Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

377. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers and Plaintiffs. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on consumers and/or the Plaintiffs.

378. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

379. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiffs as set out herein by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

380. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

d. Damages

381. The Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs injury in their businesses, as described above in language expressly incorporated herein by reference.

382. Plaintiffs' injuries were proximately caused by Defendants' racketeering activities. But for the Defendants' conduct, Plaintiffs would not have incurred the monetary losses described above and expressly incorporated herein by reference.

383. Plaintiffs' injuries were directly caused by the Defendants' racketeering activities.

384. Plaintiffs seek actual damages, treble damages, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest, which exceed the minimum jurisdictional amount for this Court to exercise jurisdiction in this matter.

COUNT II - RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT 18 U.S.C. 1962(d) *et. seq.* (Against All Defendants)

385. Plaintiffs reallege and incorporate by reference all preceding paragraphs.

386. Plaintiffs' injuries were proximately caused by Defendants' racketeering activities. But for the Defendants' conduct, Plaintiffs would not have incurred the monetary losses described above and expressly incorporated herein by reference.

387. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference below.

a. The Opioid Diversion Enterprise

388. For efficiency and avoiding repetition, for purposes of this claim, Plaintiffs incorporate by reference Paragraphs 268-299 concerning the Opioid Diversion Enterprise.

b. Conduct of the Opioid Diversion Enterprise

389. For efficiency and avoiding repetition, for purposes of this claim, Plaintiffs incorporate by reference Paragraphs 300-314 concerning the Opioid Diversion Enterprise.

c. Pattern of Racketeering Activity

390. For efficiency and avoiding repetition, for purposes of this claim, Plaintiffs incorporate by reference Paragraphs 315-380 concerning the Opioid Diversion Enterprise.

d. Damages

391. The Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs injury in their businesses, as described above in Paragraphs 381-384, in language expressly incorporated herein by reference.

392. Plaintiffs bring this claim against all Defendants. At all relevant times, the Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d) it is unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. 18 U.S.C. § 1962(d).

393. Plaintiffs' injuries were directly caused by the Defendants' racketeering activities.

394. Plaintiffs seek actual damages, treble damages, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest, which exceed the minimum jurisdictional amount for this Court to exercise jurisdiction in this matter.

COUNT III – SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT
(Against All Defendants)

395. Plaintiffs reallege and incorporate by reference all preceding paragraphs.

396. At all times relevant to this Complaint, Defendants were engaged in the trade or commerce of manufacturing, marketing, selling, and distributing prescription opioid pain medications.

397. By engaging in the acts and practices alleged herein, Defendants made or caused to be made to Plaintiffs, directly or indirectly, explicitly or by implication, misrepresentations that, reasonably interpreted, are material, false, and likely to mislead.

398. In overstating the benefits of opioids and understating their very serious risks, including the risk of addiction; in falsely promoting abuse-deterrent formulations as reducing abuse; and in falsely portraying its efforts or commitment to rein in the diversion and abuse of opioids, including in South Carolina, Defendants have engaged in misrepresentations and knowing omissions of material fact.

399. Specifically, Defendants made misrepresentations or omissions including, but not limited to:

a. the risks of long-term opioid use, especially the risk of addiction was overblown;

b. signs of addiction were "pseudo-addiction" reflecting undertreated pain, and should be responded to with more opioids;

c. screening tools effectively prevent addiction;

d. opioid doses can be increased until pain relief is achieved;

e. opioids differ from NSAIDS in that they have no ceiling dose;

f. evidence supports the long-term use of opioids for chronic pain;

g. chronic opioid therapy would improve patients' function and quality of life;

h. its abuse-deterrent opioids reduce tampering and abuse; and

i. Defendants cooperate with and support efforts to prevent opioid abuse.

400. By engaging in the acts and practices alleged herein, Defendants omitted the provision of material facts to Plaintiffs that it had a duty to disclose by virtue of Defendants' other representations to Plaintiffs, including, but not limited to, the following:

a. opioids are highly addictive and may result in overdose or death;

b. no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c. high dose opioids subject the user to greater risks of addiction, other injury, or death;

d. exaggerating the risks of competing products, such as NSAIDs, while ignoring the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines;

e. Defendants' claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f. its abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease; and may increase overall abuse; and

g. Defendants failed to report suspicious prescribers.

401. Defendants' statements about the use of opioids to treat chronic pain were not supported by or were contrary to the scientific evidence, as confirmed by the CDC and FDA.

402. Further, Defendants' omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading and likely to deceive Plaintiffs when taken in the context of the surrounding circumstances.

403. Defendants acts and practices as alleged in this Complaint had a capacity or tendency to deceive. When considered from the perspective of a reasonable Plaintiff or patient, these acts or practices were likely to mislead.

404. Defendants' acts and practices regarding Plaintiffs and patients as alleged in this Complaint are offensive to established public policy, immoral, and unethical.

405. At all times relevant to this Complaint, Defendants also violated S.C. Code § 39-5-20 by engaging in the following unfair acts or practices:

a. promoting long-term, high dose prescribing and use of opioids, in contravention of longstanding public policy to avoid and minimize the risk of addiction and abuse of controlled substances, as reflected in the South Carolina Controlled Substances Act, S.C. Code § 44-53-10 and the South Carolina Joint Revised Pain Management Guidelines approved by the S.C. Boards of Medical Examiners, Dentistry, and Nursing;

b. frustrating prescribers' ability to ensure informed consent by accurately outlining the risks and benefits of opioid use, as required by the Pain Management Guidelines set forth by the Board of Medical Examiners;

c. frustrating the public policy in favor of, and the Plaintiffs' efforts to reduce the overprescribing, overuse, misuse, and abuse of addictive prescription opioids, including through the Prescription Drug Monitoring Program, South Carolina Joint Revised Pain Management Guidelines approved by the S.C. Boards of Medical Examiners, Dentistry, and Nursing; and

d. failing to report its knowledge of suspicious prescribing in South Carolina to law enforcement or regulatory authorities, in violation of the South Carolina Controlled Substances Act, S.C. Code § 44-53-10, the State's Prescription Drug Monitoring Program, the South Carolina Joint Revised Pain Management Guidelines approved by the S.C. Boards of Medical Examiners, Dentistry, and Nursing, and as reflected as well in federal regulations requiring manufacturers and distributors of controlled substances to report suspicious orders.

406. These acts or practice were unfair in that they offended established public policy, reflected in the State's Constitution, that "[t]he health, welfare, and safety of the lives and property of the people of this State and the conservation of its natural resources are matters of public concern." S.C. Const. art. XII § 1.

407. These acts or practices were unfair in that they offended the South Carolina's public policy of preventing addiction to and abuse of controlled substances, as well as the Plaintiffs' effort to stem the harm from Defendants' deceptive and unfair acts and practices.

408. These acts or practices were unfair m that they immorally and unethically deprived prescribers of the information they needed to appropriately prescribe-or not prescribe-these dangerous drugs. Patients who use opioids can quickly become dependent or addicted, such that neither the patient nor the prescriber could avoid injury by simply stopping or choosing an alternate treatment. Defendants also immorally and unethically withheld information from authorities that they could have used to reduce opioid abuse and diversion in South Carolina.

409. These acts or practices have resulted in a substantial injury to Plaintiffs and patients that is not outweighed by any countervailing benefits to consumers or competition. Defendants' marketing has caused patients of Plaintiffs to suffer opioid addiction, abuse, overdose, death, and associated economic loss, and there is no countervailing benefit of such unsubstantiated and unbalanced marketing. Further, Defendants' failure to report suspicious prescribing has resulted in continued illicit prescribing of opioids by physicians.

410. Defendants' acts and practices as alleged herein substantially impacted the Plaintiffs' community of patients and health care providers, and caused significant actual harm.

411. Defendants' acts and practices as alleged herein were motivated by a desire to retain and increase its market share and profits. Defendants' conduct in misrepresenting and concealing the truth reflects a corrupt corporate culture that persisted over many years.

412. Defendants' deceit was substantial, and the acts and practices regarding Plaintiffs as alleged in this Complaint were undertaken in bad faith. These acts or practices were reprehensible and callously disregarded the public health and welfare. The statutory violations were especially egregious in that they represented a decision to affirmatively mislead the medical community, law enforcement, and regulatory authorities.

413. At the time Defendants made or disseminated false and misleading statements, or caused these statements to be made or disseminated, Defendants knew or recklessly disregarded that the statements were false or misleading and therefore likely to deceive the public. In addition, Defendants knew or recklessly disregarded that its false and misleading marketing, including its omissions, created a false or misleading impression of the risks and benefits of long-term opioid use.

414. At all times, Defendants knew or should have known that their conduct violated the South Carolina Unfair Trade Practices Act, and therefore was willful for purposes of S.C. Code § 39-5-110, justifying civil penalties.

415. Defendants' acts and practices regarding Plaintiffs as alleged herein are capable of repetition and affect the public interest.

416. This action seeks to protect the citizens of South Carolina, as patients of Plaintiffs, from unfair and deceptive acts in the conduct of trade and commerce.

417. Defendants' acts and practices as alleged herein have directly and proximately caused substantial injury to Plaintiffs and patients.

418. Plaintiffs and patients have suffered, and continue to suffer, ascertainable loss of money and/or property as a result of the unfair and deceptive practices alleged herein, and are entitled to restitution and/or damages for such loss.

419. Defendants' conduct was willful or knowing under S.C. Code § 39-5-140.

420. Defendants' acts or practices alleged herein constitute unfair or deceptive acts or practices in violation of S.C. Code § 39-5-20.

421. Every deceptive, unfair, and/or misrepresentative act by Defendants constitutes a separate and distinct violation of S.C. Code § 39-5-20.

COUNT IV – NEGLIGENCE (Against All Defendants)

422. Plaintiffs reallege and incorporate by reference all preceding paragraphs.

423. Under State law, to establish actionable negligence, one must show in addition to the existence of a duty, a breach of that duty, and injury resulting proximately therefrom. All such essential elements exist here.

424. Each Defendant had duties to exercise reasonable and/or due care, owed to the Plaintiffs and to the patients of the Plaintiffs in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs.

425. Each Defendant had duties to comply with the statutes, laws, and regulations of the United States as well as each state where it conducted business by selling or distributing pharmaceuticals, including but not limited to the State of South Carolina.

426. Each Defendant breached its aforesaid duties by its conduct previously identified herein.

427. Each Defendant owed its aforesaid duties to the Plaintiffs because the injuries alleged herein were foreseeable by the Defendants.

428. By violating the statutes, laws and or regulations of the United States, and each of the states where Defendants did business, including but not limited to the State of South Carolina, each Defendants' actions constitute negligence, *per se*.

429. Plaintiffs seek compensatory damages for their monetary losses previously specified herein, plus interest and the costs of this action, which exceed the minimum jurisdictional amount for this Court to exercise jurisdiction in this matter.

COUNT V – NEGLIGENCE *PER SE*
(Against all Defendants)

430. The South Carolina Legislature has declared that "[t]he Department of Health and Environmental Control shall take cognizance of the interest of the public health as it relates to the sale of drugs and the adulteration thereof and shall make all necessary inquiries and investigations relating thereto." S.C. Code Ann. § 44-53-10. As such, the South Carolina Legislature has further declared that "[e]very person who manufactures, distributes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance, shall obtain a registration issued by the Department in accordance with its rules and regulations." S.C. Code Ann. § 44-53-290.

431. To be granted such a registration, the South Carolina State Department of Health and Environmental Control must determine that the issuance of the registration is consistent with the public interest, taking into consideration the following factors: (1) Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels; (2) Compliance with applicable state or federal law; (3) Promotion and technical advances in the art of manufacturing these substances and the development of new substances; (4) Prior conviction record of applicant under Federal

and State laws relating to the manufacture, distribution or dispensing of such substances; (5) Past experience in the manufacture, distribution, and dispensing of controlled substances and the existence in the establishment of effective controls against diversion; (6) Such other factors as may be relevant to and consistent with the public health and safety; and (7) Licensing by a federal agency. S.C. Code Ann. § 44-53-300.

432. The South Carolina Legislature has declared it a felony to "furnish false or fraudulent material information in, or omit any material information from, any application, report, or other document required to be kept or filed under [South Carolina Code, Chapter 53, Article 3, Narcotics and Controlled Substances], or any record required to be kept by that article." S.C. Code Ann. § 44-53-390.

433. The South Carolina Legislature has also expressly declared that "[a]ll applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances." S.C. Code Ann. Regs. 61-4.401.

434. Specifically, the South Carolina Legislature has stated that "the security requirements set forth in S.C. Code Ann. Regs. 61-4.402-406 [shall be used] as standards for the physical security controls and operating procedures necessary to diversion." S.C. Code Ann. Regs. 61-4.401

435. Furthermore, federal law requires that Defendants maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(a)(1), (b)(1). These federal regulations impose a non-delegable duty upon both manufacturers and distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor or manufacturer] shall inform the Field Division Office of the

Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

436. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). Regardless, all flagged orders must be reported. *Id*.

437. Each Defendant was further required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Defendant is a "registrant" as a wholesale distributor and/or manufacturer in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

438. Defendants violated S.C. Code Ann. § 44-53-390, which declares it a felony to "furnish false or fraudulent material information in, or omit any material information from, any application, report, or other document required to be kept or filed under [South Carolina Code, Chapter 53, Article 3, Narcotics and Controlled Substances], or any record required to be kept by that article." S.C. Code Ann. § 44-53-390.

439. Defendants violated S.C. Code Ann. § 44-53-280, and the regulations promulgated pursuant thereto, including but not limited to S.C. Code Ann. Regs. 61-4.401, which provides that "[a]ll applicants and registrants shall provide effective controls and

procedures to guard against theft and diversion of controlled substances". S.C. Code Ann. Regs. 61-4.401

440. Defendants violated S.C. Code Ann. § 44-53-370, which makes it unlawful for any person "to manufacture, distribute, dispense, deliver, purchase, aid, abet, attempt, or conspire to manufacture, distribute, dispense, deliver, or purchase, or possess with the intent to manufacture, distribute, dispense, deliver, or purchase a controlled substance or a controlled substance analogue" outside the specific authority granted under South Carolina Code, Chapter 53, Article 3, Narcotics and Controlled Substances. S.C. Code Ann. § 44-53-370

441. Defendants violated S.C. Code Ann. § 44-53-380, which makes it unlawful for any person "[w]ho is a registrant to manufacture, distribute, or dispense a controlled substance not authorized by his registration to another registrant or other authorized person." S.C. Code Ann. § 44-53-380.

442. Defendants also violated S.C. Code § 39-5-20, as discussed in Count III, above.

443. Under South Carolina law, "Negligence *per se* is established by showing a statute created a duty to the plaintiff and the defendant breached that duty by violating the statute." *Seals by Causey v. Winburn*, 314 S.C. 416, 445 S.E.2d 94, 96 (Ct. App. 1994).

444. To show that a duty of care arises from a statute, a plaintiff must establish that: (1) the essential purpose of the statute is to protect from the kind of harm the plaintiff has suffered; and (2) the plaintiff is a member of the class of persons the statute is intended to protect. *Wogan v. Kunze*, 366 S.C. 583, 623 S.E.2d 107, 117–18 (Ct. App. 2005)

445. Plaintiffs are within the class intended to be protected by the above-referenced public safety statutes and regulations concerning controlled substances.

446. Defendants' violations of these public safety laws are *prima facie* evidence of negligence. Each Defendant had a duty under, inter alia, these laws to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids. Defendants' violations of the law constitute negligence *per se*. Defendants breached mandatory, non-delegable legal duties and did not act reasonably under the circumstances.

447. As described above in allegations expressly incorporated herein, Defendants breached their duties to maintain effective controls against diversion of dangerously addictive opioids, including violating public safety statutes and regulations requiring that, as wholesale drug distributors, Defendants could only distribute these dangerous drugs under a closed system Defendants were responsible for guarding.

448. As described above, Defendants' breach of statutory and regulatory duties caused, bears a causal connection with, is and was a substantial factor contributing to, and/or proximately resulted in, harm and damages to Plaintiffs.

449. The injuries and damages sustained are those which the above-referenced South Carolina statutes and public safety regulations were designed to prevent.

450. Defendants' violations of the above-referenced South Carolina statutes and public safety regulations cited herein were and are a substantial factor in the injuries and damages sustained.

451. It was foreseeable that Defendants' breach of statutory and regulatory duties described herein would result in the damages sustained.

452. Plaintiffs seek compensatory damages for their monetary losses previously specified herein, plus interest and the costs of this action, resulting from Defendants' negligence *per se*.

453. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including inter alia injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Manufacturer and Distributor Defendants, attorney fees and costs, and pre- and post-judgment interest, which exceed the minimum jurisdictional amount for this Court to exercise jurisdiction in this matter.

COUNT VI – WANTONESS, RECKLESSNESS, AND GROSS NEGLIGENCE (Against all Defendants)

454. Plaintiffs reallege and incorporate by reference all preceding paragraphs.

455. Defendants' aforesaid acts and omissions were done and/or omitted knowing that injury to Plaintiffs would likely or probably result; were done and/or omitted with a reckless or conscious disregard of the rights of Plaintiffs; were done and/or omitted without the exercise of even a slight degree of care; were done and/or omitted with conscious indifference to the consequences; and/or constituted a substantial deviation from the accepted and applicable standard(s) of care.

456. As a direct and proximate result of Defendants' wantonness, recklessness, or gross negligence, Plaintiffs were monetarily damaged as aforesaid. Plaintiffs seek compensatory and punitive damages, plus the costs of this action, which exceed the minimum jurisdictional amount for this Court to exercise jurisdiction in this matter.

COUNT VII – FRAUD
(Against All Defendants)

457. Plaintiffs reallege and incorporate by reference all preceding paragraphs.

458. As alleged herein, Defendants made false representations, concealed material facts about opioids, and encouraged the prescription of opioids by physicians, as well as the use of opioids by patients, even when medically unwarranted.

459. Defendants made misrepresentations and failed to disclose material facts to physicians and patients throughout the United States, to induce and encourage physicians to prescribe and administer, and patients to purchase and consume, opioids as set forth herein.

460. Defendants' false representations and omissions were material, and were made and/or omitted intentionally or knowingly.

461. Defendants intended that physicians and patients would rely upon their misrepresentations and omissions.

462. Physicians and patients reasonably relied on Defendants' misrepresentations and omissions. Physicians prescribed and administered, and patients purchased and consumed, opioids as set forth herein.

463. Because of physicians' and patients' reliance on Defendants' misrepresentations and omissions of material fact, Plaintiffs have suffered monetary damages as aforesaid. Plaintiffs seek compensatory and punitive damages, plus the recovery of costs associated with this action, which exceed the minimum jurisdictional amount for this Court to exercise jurisdiction in this matter.

COUNT VIII – PUBLIC NUISANCE
(Against All Defendants)

464. Plaintiffs reallege and incorporate by reference all preceding paragraphs.

465. Defendants, through the actions described in the Complaint, have created, or were a substantial factor in creating, a public nuisance by unreasonably interfering with a right common to the general public that works hurt, inconvenience, or damage, and interferes with the enjoyment of life or property.

466. Plaintiffs and patients have a public right to be free from the substantial injury to public health, safety, peace, comfort, and convenience that has resulted from Defendants illegal and deceptive marketing of opioids for the treatment of chronic pain.

467. This injury to Plaintiffs and patients includes, but is not limited to (a) a distortion of the medical standard of care for treating chronic pain, resulting in pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment; (b) high rates of opioid abuse and addiction, with which too many South Carolina residents will now struggle their entire lives; (c) overdoses, other serious diseases (like Hepatitis C), and fatalities, with grievous consequences to South Carolina communities and families; (d) children removed from their homes and newborns born addicted to opioids; (d) lost employee productivity due to opioid- related addiction and disability; (f) the creation and maintenance of a secondary, criminal market for opioids; (f) greater demand for emergency services, law enforcement, addiction treatment, and social services; and (h) increased health care costs for individuals, families, and the State.

468. At all times relevant to the Complaint, Defendants' deceptive marketing substantially and unreasonably interfered in the enjoyment of this public right by the Plaintiffs and their patients. Defendants engaged in a pattern of conduct that: (a) overstated the benefits of chronic opioid therapy, including a failure to disclose the lack of evidence supporting long-term use of opioids; (b) obscured or omitted the serious risk of addiction and other adverse

effects arising from such use; and (c) overstated the impact of its abuse-deterrent formulations in reducing abuse, thus prompting doctors to continue to prescribe opioids in the false belief that these opioids were safer or prevented abuse. This conduct affected and maintained a shift in health care providers' willingness to prescribe opioids for chronic pain, resulting in a dramatic increase in opioid prescribing and the injuries described above. Defendants also interfered with the enjoyment of the public right by failing to report suspicions of illicit prescribing to law enforcement.

469. At all times relevant to the Complaint, Defendants exercised control over the instrumentalities constituting the nuisance, i.e., their marketing as conveyed through sales representatives, other speakers, and publications, and their program to identify suspicious prescribing. As alleged herein, Defendants created, or were a substantial factor in creating, the nuisance through multiple vehicles, including: (a) making in-person sales calls; (b) disseminating advertisements and publications; (c) creating, sponsoring, and disseminating flawed and biased scientific research and prescribing guidelines; (d) sponsoring and collaborating with third parties to disseminate false and misleading messages about opioids; and (e) failing to report suspicious prescribing to law enforcement. To the extent Defendants worked through third parties, they adopted those third-party statements as their own by disseminating their publications, and/or exercised control over them by financing, reviewing, editing, and approving their materials.

470. Defendants’ actions were, at the very least, a substantial factor creating the public nuisance by deceiving prescribers and patients about the risks and benefits of opioids and distorting the medical standard of care for treating chronic pain. Without Defendants’ actions, opioid

use would not have become so widespread, and the opioid epidemic that now exists in the State of South Carolina would have been averted or would be much less severe.

471. The public nuisance was foreseeable to Defendants, which knew or should have known of the harm they would cause. As alleged herein, Defendants engaged in widespread promotion of opioids in which they misrepresented the risks and benefits of opioids to treat chronic pain. Defendants knew that there was no evidence showing a long-term benefit of opioids on pain and function, and that opioids carried serious risks of addiction, injury, overdose, and death. A reasonable person in Defendants' position would foresee not only a vastly expanded market for chronic opioid therapy as the likely result of Defendants' conduct—that was Defendants' goal—but also that widespread problems of opioid addiction and abuse would result. In fact, Defendants were on notice and aware of signs that the broader use of opioids was causing just the kinds of injuries described in this Complaint.

472. This public nuisance can be abated through education on appropriate prescribing, honest marketing of the risks and benefits of long-term opioid use, addiction treatment, disposal of unused opioids, and other means.

473. Because of Defendants' actions, they have created a need for Plaintiffs to provide undercompensated and/or uncompensated care to illicit drug users. Plaintiffs seek compensatory and punitive damages, plus the recovery of costs associated with this action, which exceed the minimum jurisdictional amount for this Court to exercise jurisdiction in this matter.

XIV. DAMAGES

474. As a direct and proximate result of the foregoing, Defendants have foreseeably caused damages to Plaintiffs, including but not limited to the following: (a) unreimbursed and/or uncompensated costs incurred for the treatment of patients who suffer from conditions related to or caused by opioid use; (b) unreimbursed and/or uncompensated costs incurred for the treatment of patients, whose conditions are managed through the prescribing of long-term opioid use and the complications suffered by those patients as a result of long-term use of opioids; (c) unreimbursed and/or uncompensated costs incurred for the treatment and management of patients under the influence of opioids or suffering complications as a result of opioid use or misuse; (d) unreimbursed and/or uncompensated costs incurred for the treatment of patients including children whose medical conditions and complications may be caused by or exacerbated by the use of opioids by others; (e) unreimbursed or uncompensated costs of providing additional treatments and services including therapeutic and prescription drug purchases; (f) unreimbursed and/or uncompensated costs incurred for the provision of laboratory and other diagnostic testing for the treatment and/or management of patients using opioids or undergoing therapeutic interventions to address opioid use or misuse; (g) unreimbursed and/or uncompensated costs incurred for the emergency treatment of patients with opioid-related addiction, disease, or dependency, including but not limited to emergency healthcare services provided for opioid overdose or for patients seeking treatment with opioids due to addictions, dependencies, and/or misuse; (h) unreimbursed and/or uncompensated costs incurred for the treatment with life support-related healthcare services to prevent death in certain instances of opioid overdose, including but not limited to treatment for babies born

with addictions and dependencies; (i) the increased costs due to providing necessary screening procedures for acceptance of patients due to the high prevalence of individuals suffering from opioid-related addiction, disease, or dependency and needing medical care; (j) increased costs related to the monitoring of patients; (k) increased costs related to the credentialing and monitoring of healthcare providers; (l) increased costs related to additional security to address public safety concerns, particularly in the emergency department; (m) increased costs related to the storage and safekeeping of controlled substances; (n) increased costs related to added regulatory compliance; (o) increased litigation defense costs; (p) increased costs related to the procurement and maintenance of insurance; (q) lost revenue attributable to the required discharge of patients who are diverting and/or using opioids in a manner which does not comply with their prescribed use; (r) lost opportunity costs; (s) the diversion of assets from the provision of other needed health care; (t) increased human resources costs, as well as loss of employee productivity; (u) uncompensated research cost related to non-opioid treatment alternatives; (v) uncompensated cost and expense for the provision of non-opioid treatment alternatives in the future; (w) uncompensated cost and expense for the current and future provision of treatment to address the consequences of opioid addiction and dependency, including but not limited to the after-effects attributable to medication assisted therapies; and (x) uncompensated cost and expense for the current and future provision of treatment to patients suffering from opioid withdrawal and/or medical issues related to opioid withdrawal.

XV. PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs, Bon Secours Health System, Inc.; Bon Secours - St. Francis Xavier Hospital, Inc.; St. Francis Hospital, Inc.; and St. Francis Physician Services, Inc., respectfully pray that the Court grant the following relief:

1. Provide injunctive relief;
2. Issue civil penalties;
3. Enter judgment awarding Plaintiffs monetary damages, in the form of restitution and/or an adequate compensatory amount;
4. Enter judgment awarding Plaintiffs monetary damages, punitive in nature, on their claims for wanton, reckless, and grossly negligent conduct, and on their claims for fraud;
5. Enter judgment awarding Plaintiffs treble damages on their RICO claims;
6. Award Plaintiffs pre-judgment and post-judgment interest as provided by law;
7. Award Plaintiffs reasonable attorney fees and costs;
8. A trial by jury for all counts so triable; and
9. Any and all other relief this Court deems necessary.

XVI. JURY DEMAND

Plaintiffs, Bon Secours Health System, Inc.; Bon Secours - St. Francis Xavier Hospital, Inc.; St. Francis Hospital, Inc.; and St. Francis Physician Services, Inc., demand a trial by jury on all issues so triable.

Respectfully submitted,

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